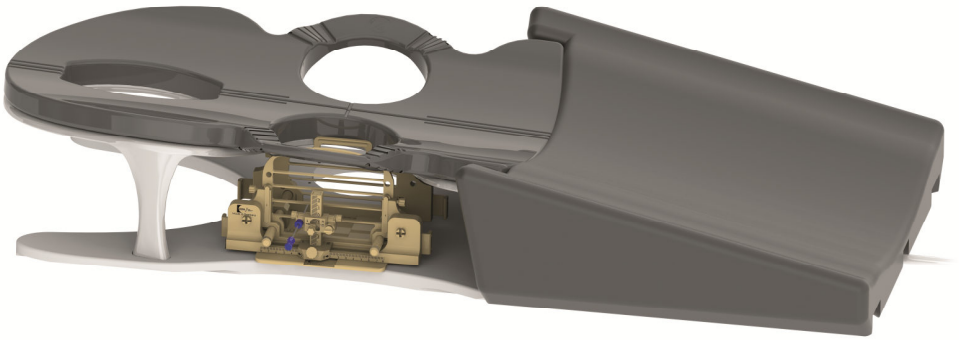
Breast Biopsy 4-Channel Coil BI 320-PA-GE 1.5T 117693

for Immobilization and MR-supported Mammography with the NORAS 4-Channel PIC Breast Coil System and PA320 Patient Rest



Operator´s Manual

Revision 03

Date issued: August 2015

Content

1 General Information

A prerequisite for safe and trouble-free operation is the proper observance of instructions, in particular the following points:

The coil system of the **Breast Biopsy 4-Channel Coil BI 320-PA-GE 1.5T** can be used with the following MRI systems:

- **1.5 T:** GE Optima MR450W

The patient rest is designed for a permissible maximum patient weight of up to 135 kg.

	**Maximum allowed patient weight**
	The maximum permissible patient weight may not be exceeded of 135 kg.

Before examination with patients, it is recommended to train on the phantom in order to be familiar with the system.

To receive information about new developments or accessories for your **Patient Rest with Immobilization and Biopsy System**, please send an e-mail with the serial number of your coil to mri@noras.de or go to www.noras.de

The application conditions have a major impact on product life. Since these conditions can vary greatly from user to user, an estimate of life time is not possible.

The most important factors in influencing product life are the frequency of application and processing method (cleaning, disinfection and sterilization).

Especially for flex coils the frequency of use and the type of application (extreme bending radius depending on the position of the examined body part) have the major influence on the life of the foam-covered as well as inside flex printed circuit board(s).

An exemplary test with the Patient Pad Coil (PPC) of the Breast Coil has demonstrated that after 3000 bending cycles and a 60-degree range of deflection upwards and downwards, the coil still works in accordance with the specifications.

Assuming of 4 applications per working day (200 days per year), the result for this test is a calculated value of almost 4 years of application without damage of the coil. This, however, is only a theoretical statement and has no representative character.

In case of rigid coils the main influence on life time is the reprocessing. Especially the use of plasma sterilization procedures reduces the lifetime considerably. A statement about the effective life time is not possible, because there is no data basic for statistical evaluation.

All further products made of plastic, the influence parameters are especially the reprocessing and the mechanical wear of moving parts. The treatment process can lead to a discoloration of the materials, but this has no influence on the material properties and product life.

Mechanical wear is dependent on the frequency of application and for the above mentioned reasons, it cannot be assessed quantitatively.

Safety:

Take into account the intended use and specified warnings in the manual, as well as performing of visual inspection for all components before using the product on the patient.

	**Notice**
	Please follow the safety instructions of MRI manufacturer for operators, patients and third parties.

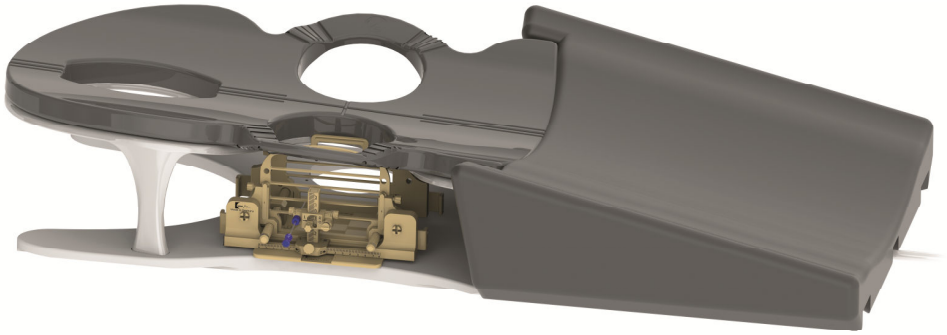
 G13	**Prescription use only** Country specific laws restrict this device to sale by or on the order of a physician, or with the descriptive designation of any other practitioner licensed by the law of the country in which he practices to use or order the use of the device. This device may only be distributed to persons who are licensed practitioners or to persons who have a prescription or other order from a licensed practitioner to purchase it.

2 Intended Use / Indication for Use

The intended use of the **Breast Biopsy 4-Channel Coil BI320-PA-GE 1.5T** is, in conjunction with a Magnetic Resonance Scanner, the MR examination of the female breast.

It is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal ad oblique images of the internal structures of the female breast. When interpreted by a trained physician, these images provide information that can be useful in determining diagnosis.

The **Biopsy Unit** permits MR guided breast biopsy and wire localization of lesions can be performed by a trained physician.



2.1 Indications

- Tumor recognition in the case of unclear diagnoses from other diagnostic procedures using contrast agents and their decay times.
- Breast biopsy, i.e. biopsy from lateral, medial and cranio-caudal direction.

2.2 Contraindication

All patient examinations are contraindicated with this system which is also contraindicated in the proximity of the MRI device according to the information provided by the manufacturer. Furthermore, the responsibility lies with the examination physician in case of unclear or critical clinical picture.

	**Notice**
	Please follow the safety instructions of MRI manufacturer for operators, patients and third parties.

3 Function

The **4-Channel Breast Coil System** described in this document has been designed for use with a MRI system with field strength of 1.5T.

The coil system consists of pure receiving coils for the reception of high frequency signals from the hydrogen-(^{1}H)-nuclei. The hydrogen nuclei are induced into precession by the transmitting coil of the MRI device.

The precessing magnetization induces potential differences in the **4-Channel Coil** which are digitized and further processed in the MRI system.

The **Breast Biopsy 4-Channel Coil BI 320-PA-GE 1.5T** consists of a **Patient Rest with Immobilization, Biopsy and Breast Coil System**. Imaging is performed with a 4-Channel “phased array“ coil (consisting of two coil pairs) developed and manufactured by the NORAS company. Interconnection is handled by the software of the MRI.

The 4-Channel mammographic coil offers flexible use to meet the needs of the procedure to be performed in your clinic. The upper 2-channel “Pad Coil” can be supplied as a 1.5T model. It is removable and enables the biopsy device to be used with the respective corresponding coil with the different field strengths.

The both channels in the lower area are firmly integrated in the patient rest and can be combined for imaging with the upper 2-channel patient pad coil. That way the two devices form a high resolution, 4-channel “phased array” configuration.

In addition, thanks to the slightly tilted design of the patient rest, generous cranio-caudal access space is available for breast biopsies. Additional access space is gained in the rear area for improved operator’s manual access by the user.

The Immobilization Device can be rotated by 360°. This ensures optimum access to the lesion (ca. 270°). For guidance, a telescopic assembly, the Post & Pillar System, provides access also to regions very close to the chest wall (Axilla). An additional access possibility is offered by the alternative use of the compression plates and needle blocks. Biopsy access is single-sided medial, single-sided/double-sided lateral or single-sided/double-sided cranio-caudal.

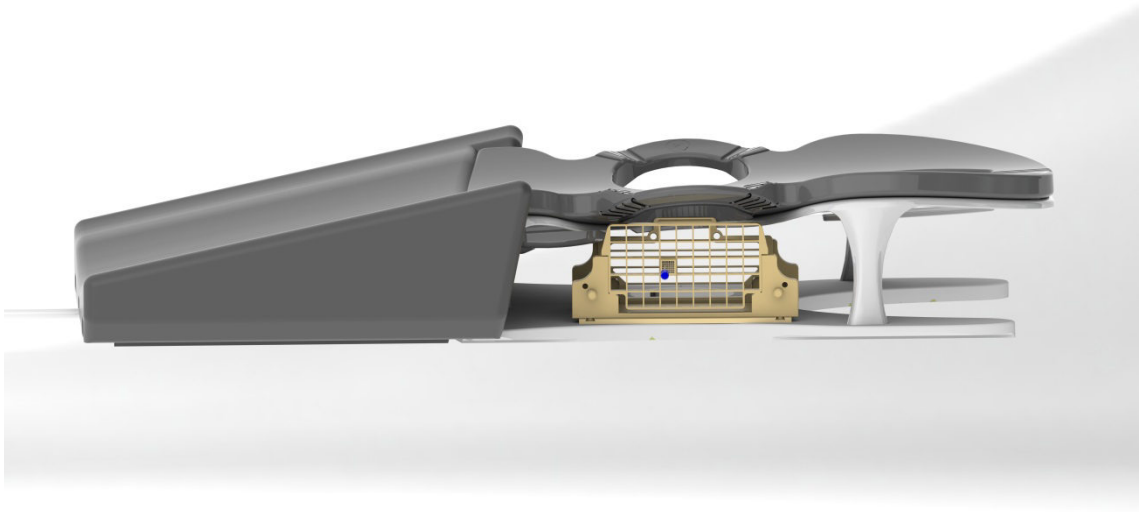


Image similar

3.1 Safety Concept

The following safety concept must be strictly followed while performing a biopsy:

A control scan must be made after each work step to verify the correct completion of the previous work steps to be able to recognize incorrect adjustments of the needle guides bases and needle blocks during the biopsy. That is the only way to recognize incorrect adjustments, incorrectly read scale values and other operator errors in order to prevent injuries to the patient.

The control scan procedure is described in Chapter 6 “Localization and Biopsy Process“ and the correct result illustrated in the text.

4 Device Description

4.1 Definitions and Symbols

The following symbols are used on the **Breast Biopsy 4-Channel Coil BI 320-PA-GE 1.5T** and in this operator´s manual:

	ISO 7000-2497	Date of Manufacture
	DIN EN 980 (5.12)	Manufacturer
	EN ISO 7010-M002	Operator's Manual Differ to the requirements of EN ISO 701-M002 all laser engravings can only be executed in grey instead of blue due to technical unfeasibility
	ISO 7000-0434B	Caution, read the accompanying documents
	Directive 2002/96/EC	Waste products should not be disposed of with household waste e. g. at a local authority collection point
	ISO 780 DIN 55402	This way up
	ISO 7000-0621	Fragile, handle with care
	ISO 7000-0626	Store in a dry place
	ISO 7000-0632	Temperature Limit
	ISO 7000-2498	Serial Number
	DIN EN 980 (5.10)	Item Number

	IEC 60417-5172	Protective Insulation
	IEC 60417-5333	Type BF
		Do not touch!
		Conforms to the essential requirements of Council Directive 93/42/EEC of 14 June1993 concerning medical devices.
		Warning regarding risks that may result in minor physical injury or material damage.
		Warning regarding risks that may result in death or serious physical injury.
		Information regarding the optimal use of the product.

On the following page we describe where you can find our various rating plates on your product. In addition to the above described symbols, you will also find the model, product and serial number on these plates.

4.1.1 Rating Plates

Base Plate

The rating plate is located on the underside.

Grid Biopsy Unit: lateral, medial, cranio-caudal

The rating plate is located on the upper right.

Post & Pillar Positioning Unit

The rating plate is located on the telescopic square outside.

Patient Rest

The rating plate is located on the underside.

Patient Pad Coil

The rating plate is located on the housing cover.

Positioning Device Big Punch

The rating plate is laser engraved on the guide bar, lengthwise.

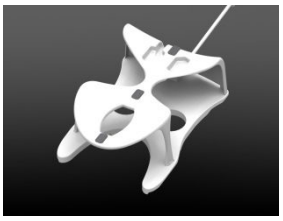
Needle Carriage Ethicon

The rating plate is laser engraved on the needle carriage.

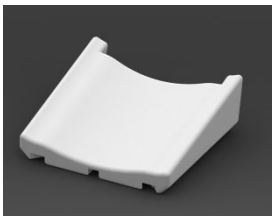
4.2 System Components

4.2.1 Patient Rest with Breast Cushion and Head Rest

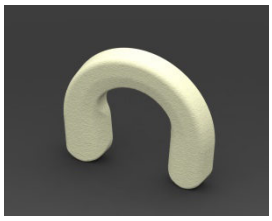
The upper part of the Patient rest is made of Polyphenylene Sulfide Resins (PPS). The bottom part is machined out of PC-GF Lexan-505RU. The surface has been finished with two-component coating. The breast cushion and the head rest are made of PE.



Patient Rest
Ref. 117720



Breast Cushion
Ref. 114971

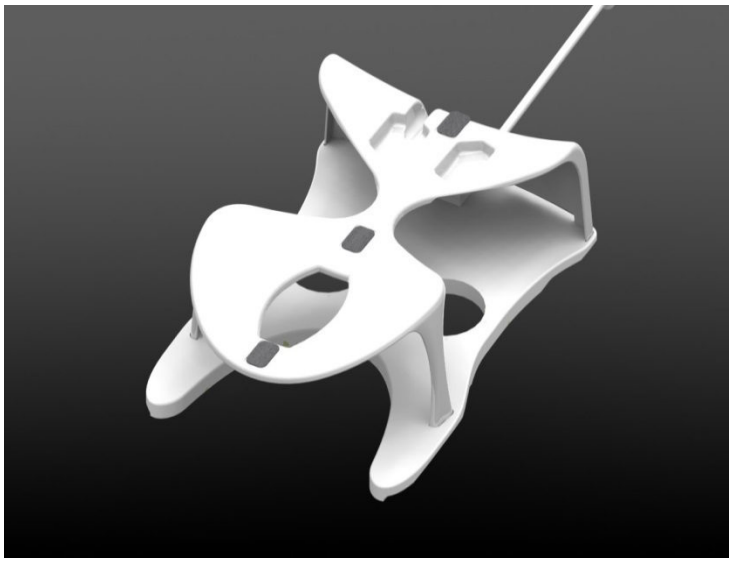


Head Rest
Ref. 117758

4.2.1.1 Coils

4.2.1.2 Bottom Array Coil (FBC – Frame Breast Coil)

The bottom array coil is firmly integrated in the patient rest and cannot be removed.



4.2.1.3 Patient Pad Coil - PPC

The Patient Pad Coil (PPC), which is made of PE foam with a PUR coating (skin-foam), serves as a positioning pad for the patient at the same time.

The both parts of the coil are connected with the connector plug at the end of the patient rest. It should be noted that the rotation position of this connector plug is correct.

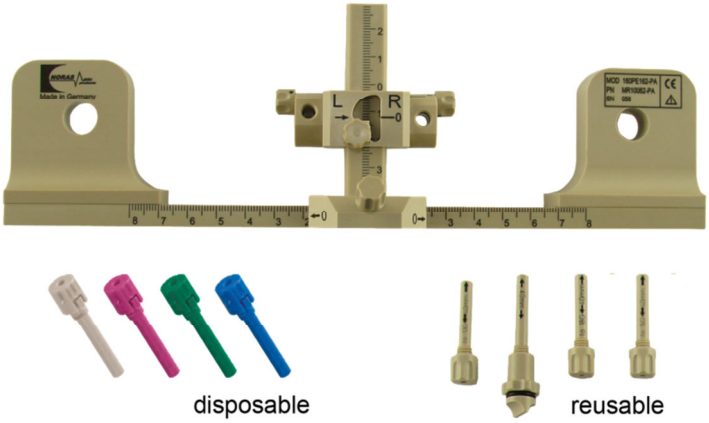
4.2.2 NORAS Biopsy Kit Modular

Throughout our modular system, you can assemble your biopsy units according to your preferences.

a) What is your preferred Biopsy Method?

Post & Pillar (with Post & Pillar Biopsy System: lateral, medial, cranio-caudal)

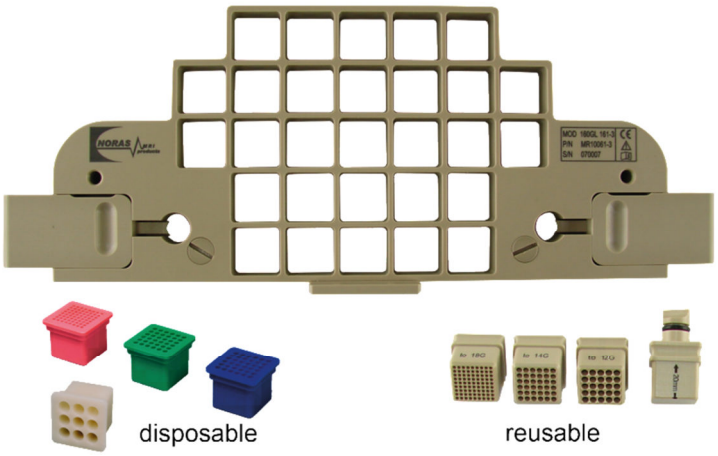
Higher accuracy compared to grid biopsy. Angulation is possible.



With our Post & Pillar System (lateral, medial, cc) you can perform exact biopsies. The needle sleeve is adjustable by 15° or 30° towards posterior or anterior. Biopsies can be performed using either reusable (autoclavable) or disposable (sterile) Post & Pillar needle guide sleeves. Various height-adjustable horizontal and vertical slat plates can be used to fixate the breast.

Grid Method (with Grid Biopsy System: lateral, medial, cc)

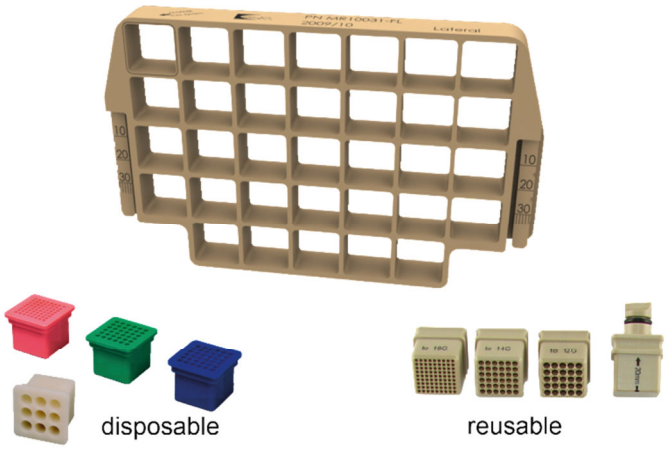
Perform several biopsies or wire placements at various lesions in one step.



The Grid Biopsy System (lateral, medial, cc) like all grid solutions, allows multiple biopsy access points within a single procedure. It is possible to perform biopsies from all sides. The unit can rotate 360° in 15° increments. Grid needle blocks can be freely positioned in the grid to ensure needle guidance. The cubes are available as reusable (autoclavable) or disposable (sterile) accessories.

Grid Method (with Grid Biopsy System Height Adjustable: lateral)

Perform several biopsies or wire placements at various lesions in one step.

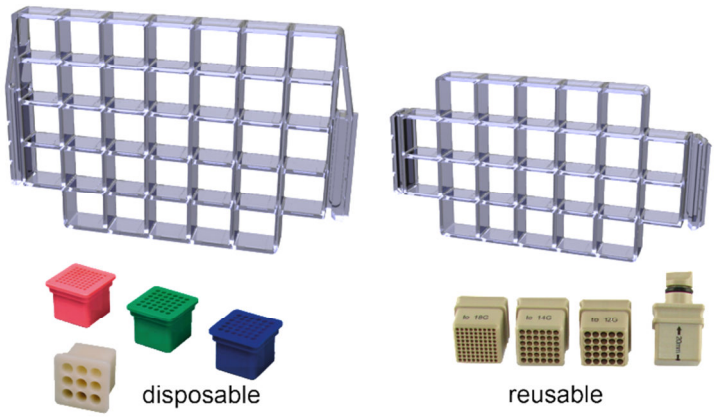


The Grid Biopsy System Height Adjustable (lateral) guarantees ideal lateral access. In particular, areas close to the thorax can be well targeted with this grid solution.

A grid needle block set, consisting of 18G, 14G and 12G tubes, is available as reusable (autoclavable) or disposable (sterile) version. The fixation of the breast is done through the grid on the lateral side and horizontal or vertical slat plates on the medial side.

Grid Method (with Grid Biopsy System Height Adjustable: lateral, medial, cc, disposable)

Perform several biopsies or wire placements at various lesions in one step.



The two Grid Biopsy Units Height Adjustable (lateral, medial, cc; disposable) offer a cost effective alternative for a lateral, medial and cranio-caudal breast biopsy application. The low priced disposable grids reduce autoclavable costs and improves patient throughput. The height-adjustable design guarantees best access. Biopsies and wire placements can be performed by either reusable (autoclavable) or disposable (sterile) grid needle blocks.

	**Warning**
	Before use, the sterile disposable grids must not come into contact with unsterile or contaminated components.

	**Warning**
	Before using the sterile disposable grid the instructions for use must read in full and with care. The sterile packaging and the instruments must be checked for proper condition

	**Warning**
	The sterile disposable grid is for single use only; it is not resterilizable and must be properly disposed after use.

	**Note**
	Only qualified personal should use sterile disposable grid.

	**Note**
	Please always wear protective gloves and carefully comply with the application times for Hepatitis B and HI viruses. (See the instructions for use of the respective disinfectant solution).

b) Modular NORAS Biopsy Units

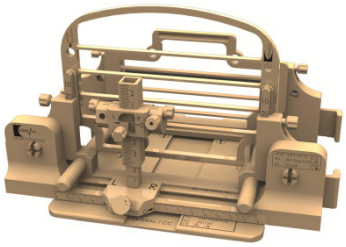
Compatible with all NORAS 4-Channel Breast Coils and NORAS Patient Rests BI320-PA. Usable for immobilization and MR guided biopsy.

Our biopsy system consists of superior plastics (PEEK) and can be used for all traditional sterilization processes (autoclavable). One has the option to purchase disposable grids for medial, lateral and cranio-caudal use for the height-adjustable grid-units. The functional unit can be build cost effectively and can be extended based upon request.

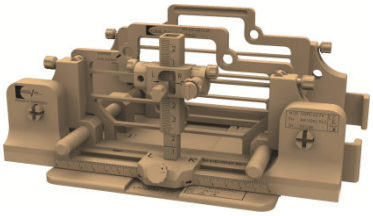
Application Examples

Modular set-up.

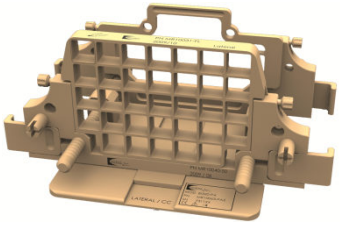
To fixate the breast, several of height-adjustable horizontal and vertical slat plates can be used as well as a medical disposable grid or the reusable grid. To perform biopsies, one can choose from the Post & Pillar or Grid Method.



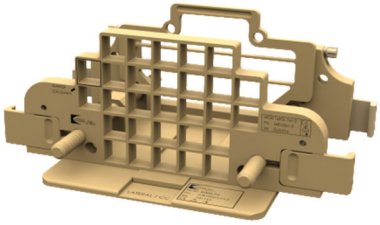
Post & Pillar Biopsy System lateral with one lateral horizontal slat plate and one medial horizontal slat plate to fixate the breast.



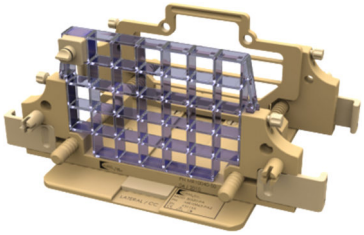
Post & Pillar Biopsy System medial or cranio-caudal with two medial horizontal slat plates to fixate the breast.



Grid Biopsy System lateral with height-adjustable lateral grid and medial horizontal slat plate to fixate the breast.



Grid Biopsy System lateral, medial or cranio-caudal with grid and medial horizontal slat plate to fixate the breast.



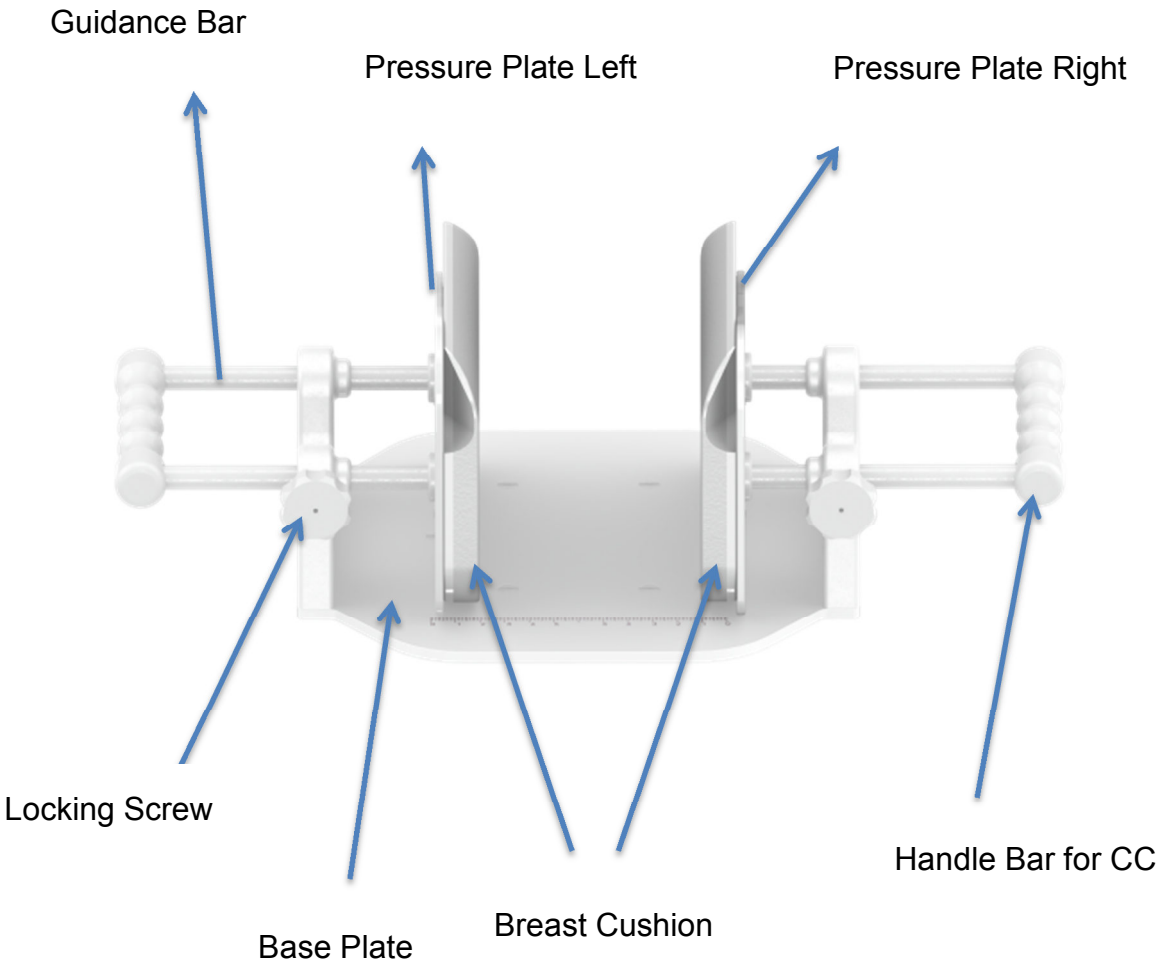
Grid Biopsy System lateral with disposable lateral grid and medial horizontal slat plate to fixate the breast.

4.2.3 Accessory: Cranio-caudal Fixation Unit CC-320-PLUS

Ref. 118341

In order to immobilize one or both breasts in cranio-caudal direction at the same time, you will need the Cranio-caudal Fixation Unit developed by NORAS. This accessory is optionally available at NORAS.

The Cranio-caudal Fixation Unit consists of one base plate, two pressure plates (left and right) with breast cushions, which enables, through the guidance bar and the affixed handle bars, the fixation. The proper adjustment is achieved by two locking screws.



4.2.4 Combination with other Devices

The coil system of the **Breast Biopsy 4-Channel Coil BI 320-PA-GE 1.5T** can be used with the following MRI systems:

- **1.5 T:** GE Optima MR450W

Special NORAS adapters are available for the use with Bard Vacora®, Suros ATEC™ und SenoRx EnCor® biopsy systems. The respective adapters for the grid system must simply be inserted in the desired position of the grid. Be sure that the adapters are firmly seated. With the help of the MRI software you can determine the correct gauge hole through which the needle must be guided.

The Post & Pillar adapters are attached to the guide base and can thus serve as a needle guide.

The adapters are indicated in Chapter 9.4 “Options and Accessories“.

The Mammotome® MR Biopsy System from Ethicon, Endo-Surgery Inc. (FDA: K042753) can be used with a special adaptor. For more information see Chapter 6 “Localization and Biopsy Process“.

Upon request, suitable adapters for your system can be manufactured.

 G39	**Combination with other devices** The **Breast Biopsy 4-Channel Coil BI 320-PA-GE 1.5T** may only be used in combination with the above-named devices and coil as well as accessories supplied by NORAS MRI products GmbH. The use of accessories supplied by other manufacturers is only permitted with the express written approval of NORAS MRI products GmbH.

	**Bodily injuries due to accessories**
	Please follow the instructions of the accessory manufacturer. In case of biopsy needles note in particular the authorization of the field strength of the used MRI and the correlation of needle diameter and needle guide/needle block and an adequate needle length for the planned biopsy (see also Chapter 6). Non-compliance with theses instructions may lead to bodily injuries of the user or patient.

 G31	**Bodily injuries due to accessories**
	When using accessories please always observe the manufacturer's instructions.

5 Start Up

5.1 General Information

	**Device damage / coil error**
	Do not bend the patient pad coil. Never carry the patient pad coil by using the loops as handles! To release the patient pad coil from the patient rest, do not pull at the coil loops! There is a risk of damage to electronic components, and thus the total failure of the breast coil.

 G19/G33	**Device damage / coil error**
	Only trained personnel may be assigned to handle the **Breast Biopsy 4-Channel Coil BI 320-PA-GE 1.5T**. Operating errors may cause permanent damages to the device/coil.

	**Bodily injuries**
	Only trained personnel may be assigned to handle the **Breast Biopsy 4-Channel Coil BI 320-PA-GE 1.5T**. Operating errors may cause bodily injuries (e.g. contusions) to the user and/or patient.

 G09	**Danger of infection** Prior to start-up of the devices or parts thereof, all components must be treated as described in chapter 7 “Cleaning, Disinfection and Sterilization“. Non-compliance with the above instructions may lead to infection of the patient.

	**Notice** Please be sure to pay attention to and comply with the safety information and instructions of the MRI device manufacturer for operators, patients and third parties.

The operator´s manual must be read by each operator prior to using this device. In order to become skilled in the proper handling of this system you should, in addition to participating in training with the system, use a phantom to become familiar with its use.

 G18	**Bodily injury of the patient** Prior to each patient examination, you should make a careful visual inspection of the system components. In case of unusual findings and/or damage found the system must not be used. Damaged parts can be sharped-edged and cause injuries to the patient and/or to the user. Do not use damaged coils. Do not produce images with a defective coil.

Assemble the desired configuration of the biopsy device. While pushing it onto the fixation plate, be sure the positioning system is pushed on as far as it will go. You can check this by listening for an audible click.

Insert the biopsy device into the insertion opening provided. Ensure that the device is firmly seated.

Position the patient rest with coils and the immobilization and biopsy device on the MRI table.

Place the patient pad coil on the patient rest. In doing so, the amplifier covers must be placed in the openings provided in the patient rest!

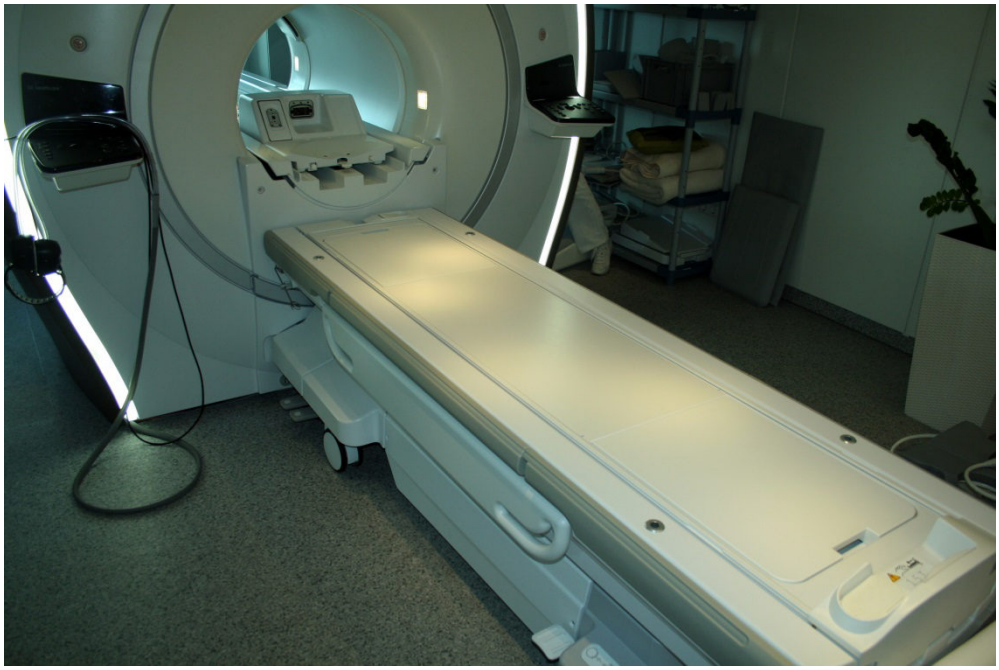
	**Notice**
	Firmly press the Velcro® tape while positioning the patient pad coil so that the pad cannot slip out of position.

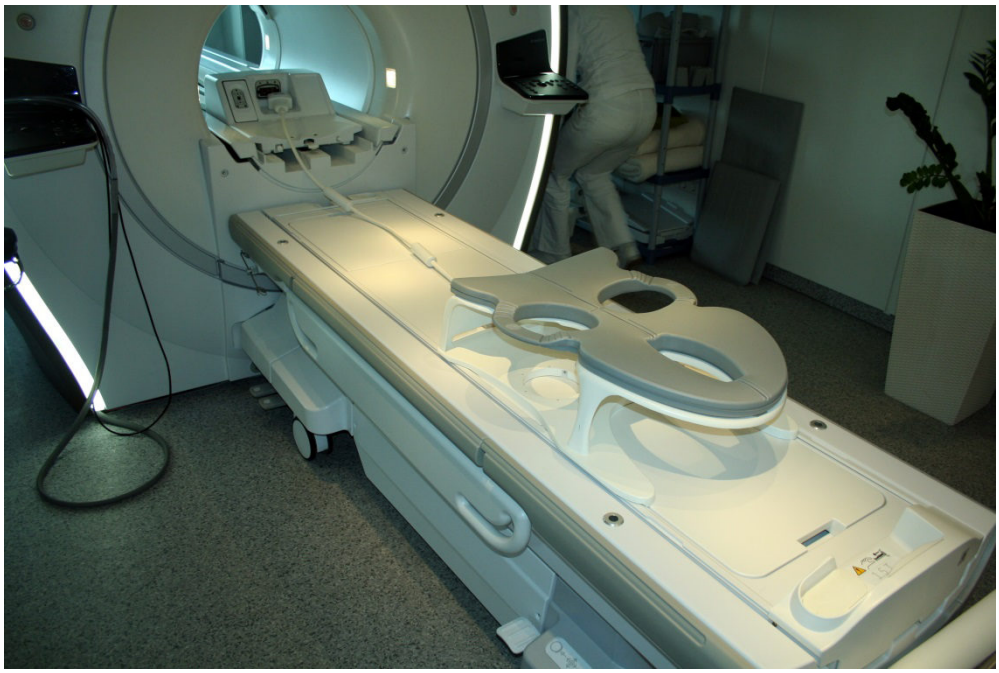
Only use sterilized needle guides or needle blocks.

The cable trap must be aligned as closely as possible parallel to the magnet opening and not perpendicular to it.

5.2 Plug-in and unplugging coils

Plug-in both coil plugs into the connections provided on the MRI table (on or off).





After plug-in the coil a green LED lights up. The coil is identified and ready for measure.

 G27	**Prolongation or termination of the treatment**
	While plugging-in the coil pair, ensure and check proper contact has been made. Check the display of the MRI. If the coil pair is not properly plugged-in, no images can be produced.

The **Breast Biopsy 4-Channel Coil BI 320-PA-GE 1.5T** is recognized by the MRI software. The software operation is described in the GE MRI operator´s manual.

 G36	**Defective coil** To remove the plugs, only push on the plug-cover themselves, do not pull on the plugs or on the cables! Non-observance of this instruction may cause cracks in the cable or in the plug. Defective coils (cables and plugs are part of the coils!) must not be used!

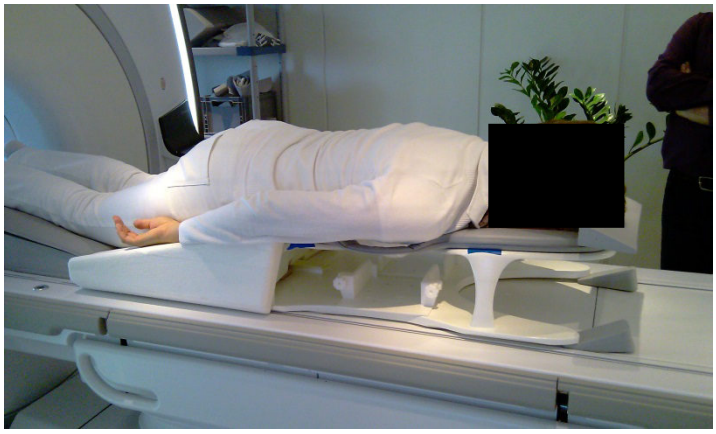
	**Risk of destruction** Pay attention and comply with the cleaning and disinfection instructions contained in this operator´s manual (see chapter 7 “Cleaning, Disinfection and Sterilization“). Coils must not be held under water! Non-compliance with the instructions in chapter instructions contained in this operator´s manual (see chapter 7 “Cleaning, Disinfection and Sterilization“ of this operator´s manual may destroy the coils.

5.3 Positioning of the Patient Rest

5.3.1 Feet First

Position the system on the MRI table and plug-in the coil plug as shown in the illustration.

Position the system at the desired location and place the wedge cushion on the MRI table in such a way that the cable lie in the cable guide of the cushion.



Patient positioning:

Place the patient in prone position, with the breasts in the open area.

Patient positioning with arms over the head:

Please take care that the patient does not place his extremities in such a way that they form a closed circle/loop. A closed circle/loop might result in RF burns of the patient.

To avoid this, please place an adequate cushion between the hands.

Use adequate positioning cushions.

Position the coil at the magnet by means of the laser sight on the Patient Pad Coil. The laser sight has to be aligned with the center of the coil.

5.4 Marker Filling Instructions

The product is delivered with unfilled markers. The number of markers required depends upon the individual type of system used (One marker is needed for manual localization; up to four markers are needed for software supported localization). Please pay attention to the following marker refilling instructions:

5.4.1 Opening Markers

Open the Post & Pillar Marker, the Grid Marker Block or the Bolt Marker by hand. To open the marker cover in the grid use a screwdriver with a blade width of 8.6 mm and to open the cover of the cartridge marker use a screwdriver with a blade width of 5.6 mm.

The cartridge marker can be released either with a screwdriver or with a needle sleeve of the unit.

Be sure to use only MR compatible screwdrivers. If no MR compatible screwdrivers are available, you must fill the oil marker outside of the MR room!

Post & Pillar Marker and Grid Marker-block

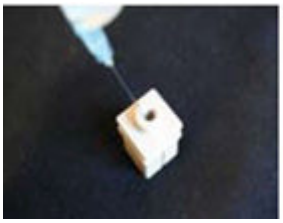
Marker Bolt

Marker with Grid

Cartridge Marker

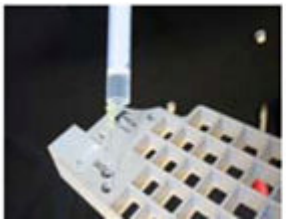
5.4.2 Filling Markers

The markers must be filled with diluted MRI contrast agent to make them visible in the MRI. To do so, fill a syringe with contrast agent (diluted 1:200) and then slowly fill the marker with the syringe up to the edge of the marker thread starting at the bottom of the marker. Rotate the syringe during filling to prevent the formation of bubbles.



Grid Markerblock

Marker Bolt

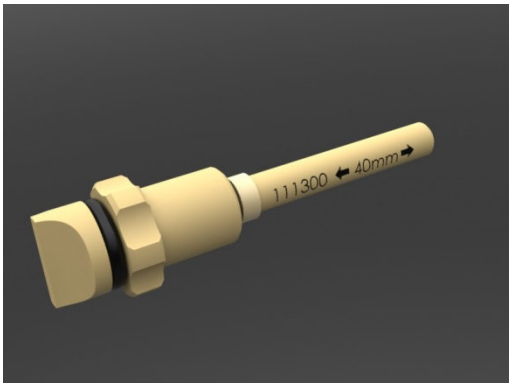


Marker inside the Grid

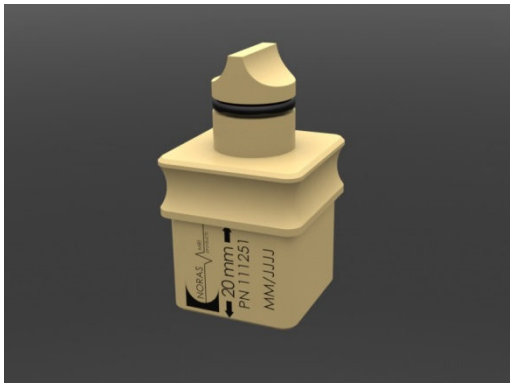
Cartridge Marker

5.4.3 Closing Markers

You can close the Post & Pillar Marker, the Grid Marker Block or the Bolt Marker by hand.



Post & Pillar Marker



Grid Markerblock

To close the marker cover in the grid use a screwdriver with a blade width of 8.6 mm and to close the cover of the cartridge marker use a screwdriver with a blade width of 5.6 mm. Be sure to use only MR compatible screwdrivers. If no MR compatible screwdrivers are available, you must fill the oil marker outside of the MR room!

Test Measurement

Test marker imaging by installing the biopsy system and taking a test measurement. The markers must be homogeneously imaged. They must not exhibit any “holes” which are air bubbles (which can also be recognized as a “kink” in the marker).

If the marker cannot be imaged as a straight line, then change the phase code direction during imaging and verify the changed settings.

5.4.4 Emptying Markers

Markers must be emptied prior to sterilization! To empty them, open the markers as described above and empty them (Caution! Marker liquid is harmful, see warning instruction). Use a syringe (filled with distilled water) to rinse out the markers starting at the bottom of the marker to remove any residual marker liquid. Then dry them or open and place them in upright position within in the steam autoclave.

	**Health hazard for operator**
	Marker liquid is harmful! Please note the warnings!

6 Localization and Biopsy Process

The biopsy procedure is based upon the safety concept described in chapter 3 “Function“. Compliance with this concept is mandatory.

	**Permanent damage to the system**
	The fixation screws should be removed from the basic unit fixation plate during medial application. In case of a higher load on the patient rest a damage of the screws could not be excluded.

When using the grid as a medial application the fixation screws must not be mounted. The screws are only necessary as additional fixation of the grid for the lateral application. The medial grid is always mounted in the lowest possible position. It is sufficiently fixated with the ball catch.

The fixation screws are part of the standard delivery of the basic unit fixation plate. The basic unit fixation plate can be used both lateral and medial. Using the grid in lateral position it can be moved in 10mm steps up to max. 30 mm in posterior direction. Only with this application, the screws are necessary for a safe fixation.

6.1 With Post & Pillar Biopsy System

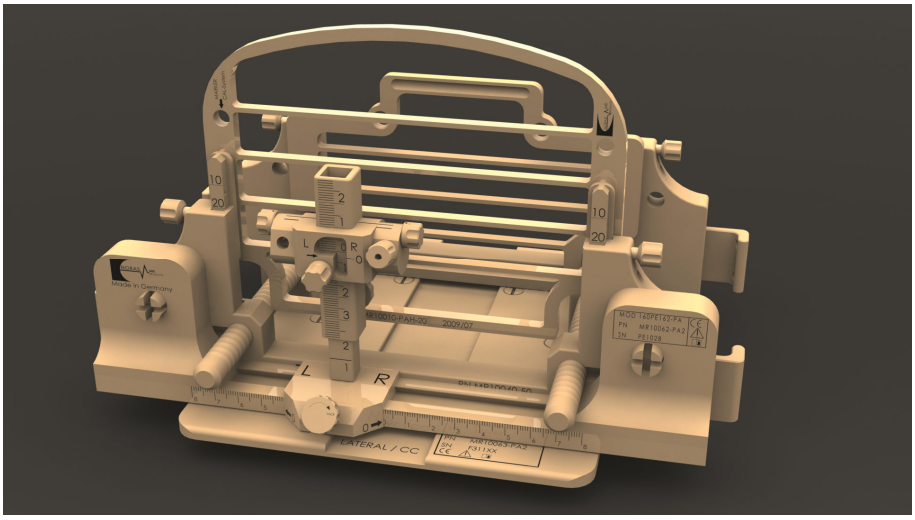
	**Permanent damage to the system**
	The system may only be assembled by trained medical personnel. Incorrect assembly and operator errors made by untrained personnel can permanently damage individual parts of optional components and of the device itself.

 G20/G40	**Training of personnel**
	The users must be trained before using the device (detailed training of the personnel for existing components).

In the following, the localization process with medio-lateral alignment of the fixation unit, lateral access and the use of axial slices is described. The description applies for the use of the system with the Post & Pillar Biopsy System for the examination of a single breast.

Medial and lateral access:

Push the fixation plate with the medial slat plate onto the shorter raster bars of the base plate (Ref.111292) as far as it goes.



Slide the second fixation plate with the curved slat plate onto the longer raster bars of the base plate (marked “Lateral/CC”) up to the stop. Insert the base plate into the round pits of the insertion plate of the patient rest.

After aligning the complete fixation unit in medio-lateral direction, slide the fixation plate until the end of the raster bars. The fixation unit is now open as far as possible.

For medial access, insert the blocking plate into the patient rest of the side of the breast which is not to be biopsied. Now position the patient on the patient rest and fixate the breast to be biopsied by pressing the slat plates on the raster bars against the breast.

Be careful to ensure that the patient can lie as comfortable as possible during the entire procedure. Now you have medial access below the blocking plate or lateral access from the outside.

Zugang cranial/caudal:

To enable cranial/caudal access proceed as described previous to provide medial/lateral access.

Please note that when the biopsy device is turned into the cranio-caudal direction, the MRI images must be made in the sagittal direction to correspond with the following description.

	**Skin contact**
	During the examination some parts of the breast may come into contact with the surface of the base plate with the low probability. Before each examination of the patients, the base plate must be covered with a clinical cloth.

 G23	**Needle penetration at incorrect location**
	The breast must be correctly immobilized. If the breast is not immobilized properly, it might slip and the data delivered by the MRI might be inaccurate.

Ensure that as much breast tissue as possible is held between the slat plates.

Screw the filled marker into one of the needle guides (on right or left side) and reset the scales of the guide base, guide bar and the angulation angle of the needle guide of the Post & Pillar positioning unit in horizontal and vertical direction to zero (*see ill. below*).

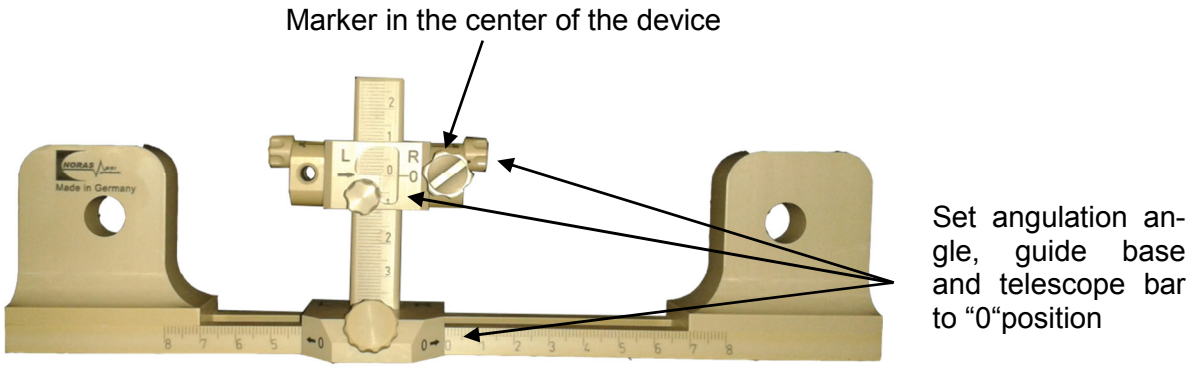
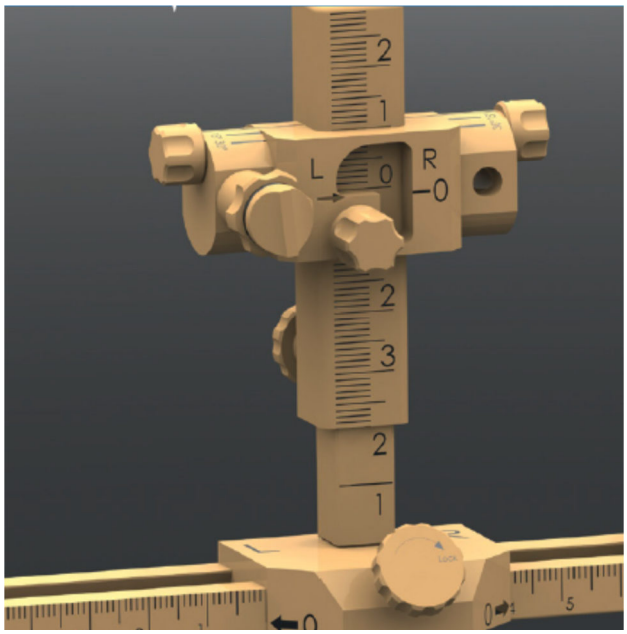
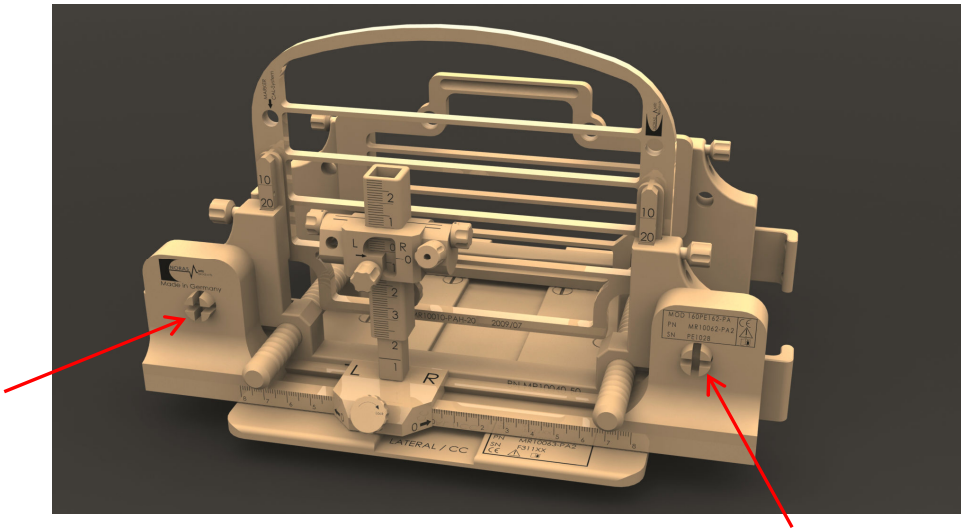


Figure above: Needle guide on zero position with marker on the right

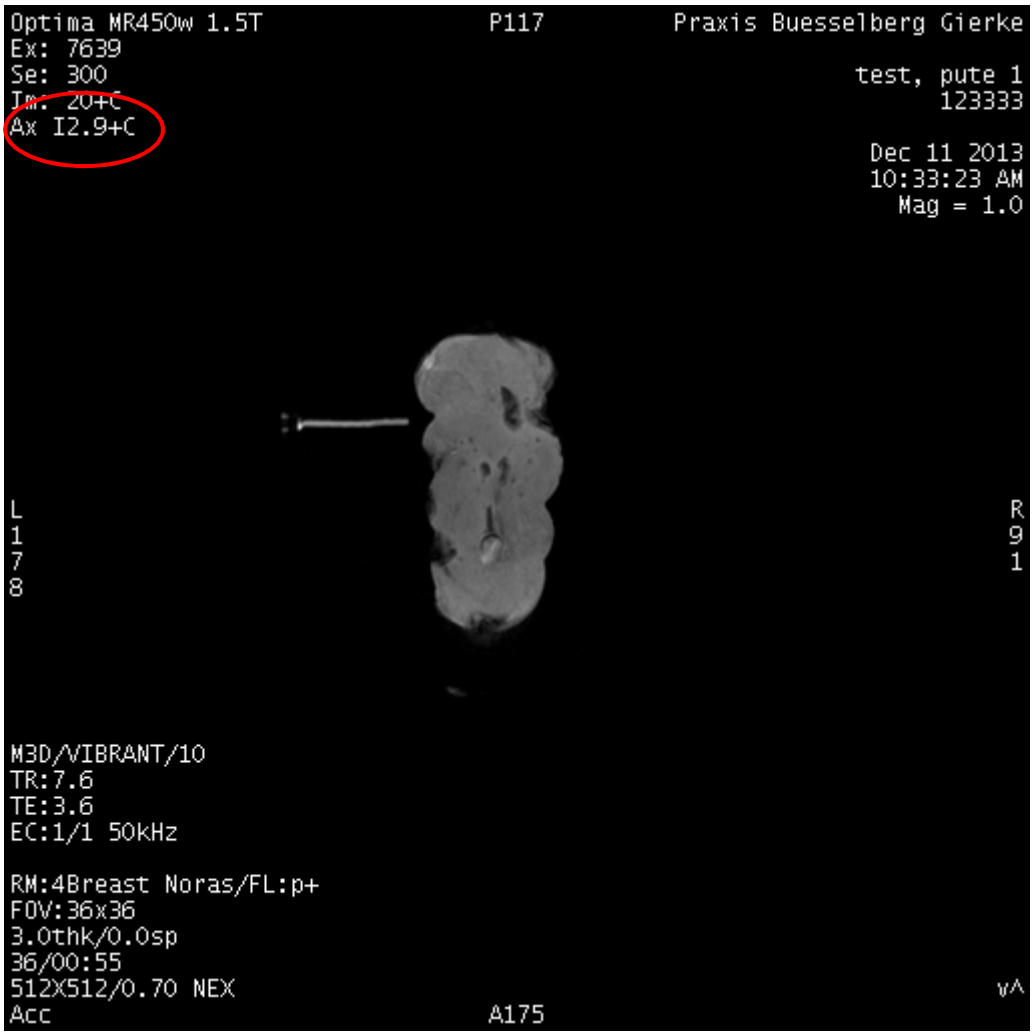


Now mount the Post & Pillar positioning unit onto the pins of the fixation plate.


L
R
LATERAL / CC

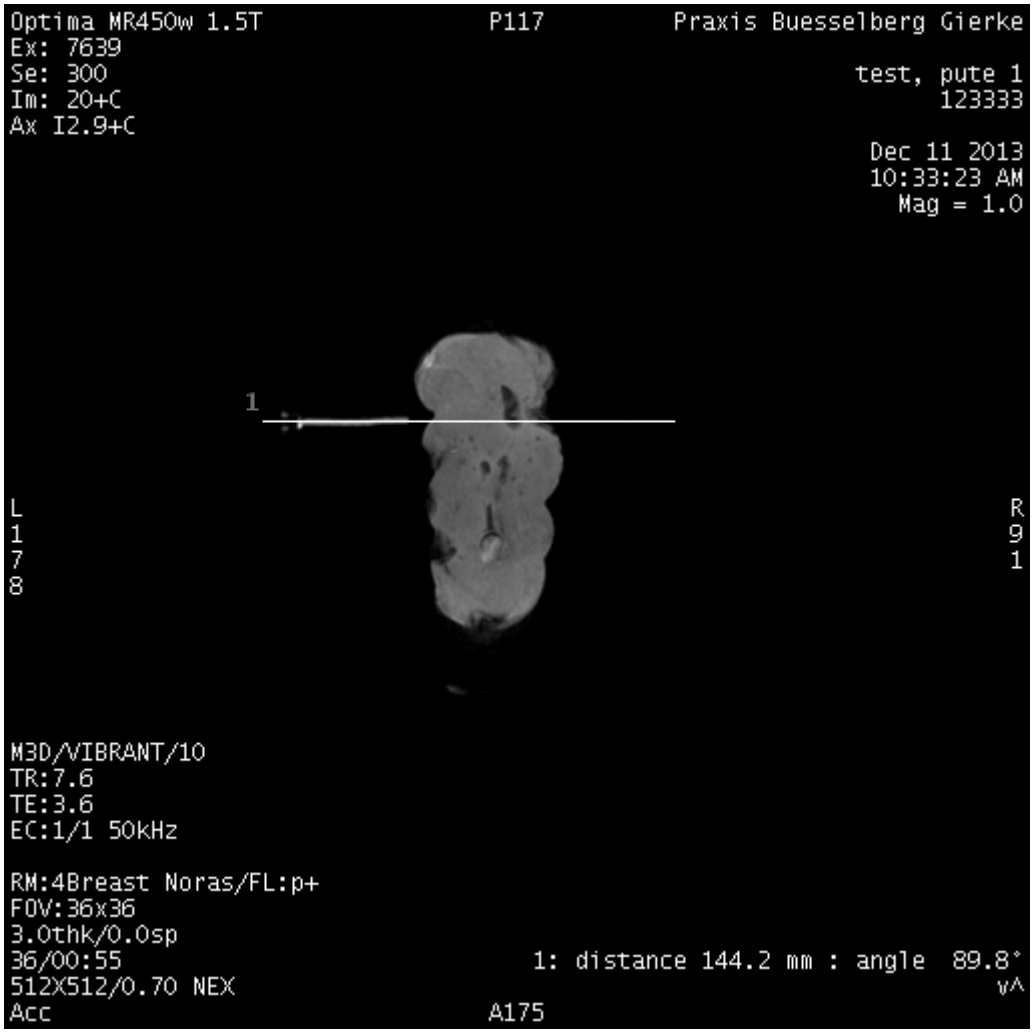
a) Manually calculation of coordinates for the MR-supported breast biopsy with the NORAS Post & Pillar Biopsy Unit on GE MR systems

1. Perform a measurement with transversal slices and look for the slice where you can see the marker.



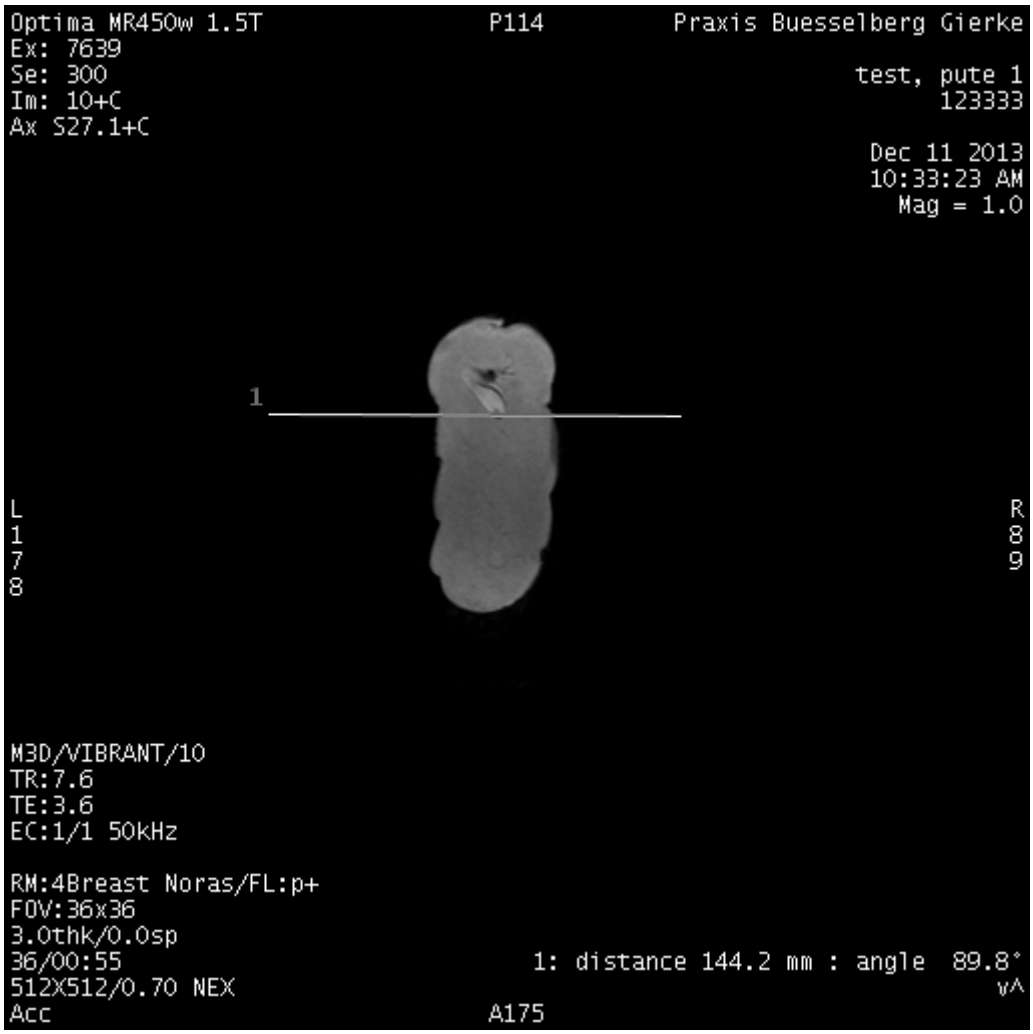
2. Start the “distance“ tool.

3. Draw a line, straight through the pointer.



4. Mark this line and copy it.

5. Scroll through the other slices until you find the lesion that you want to perform a biopsy on. In this slice paste the copied line.



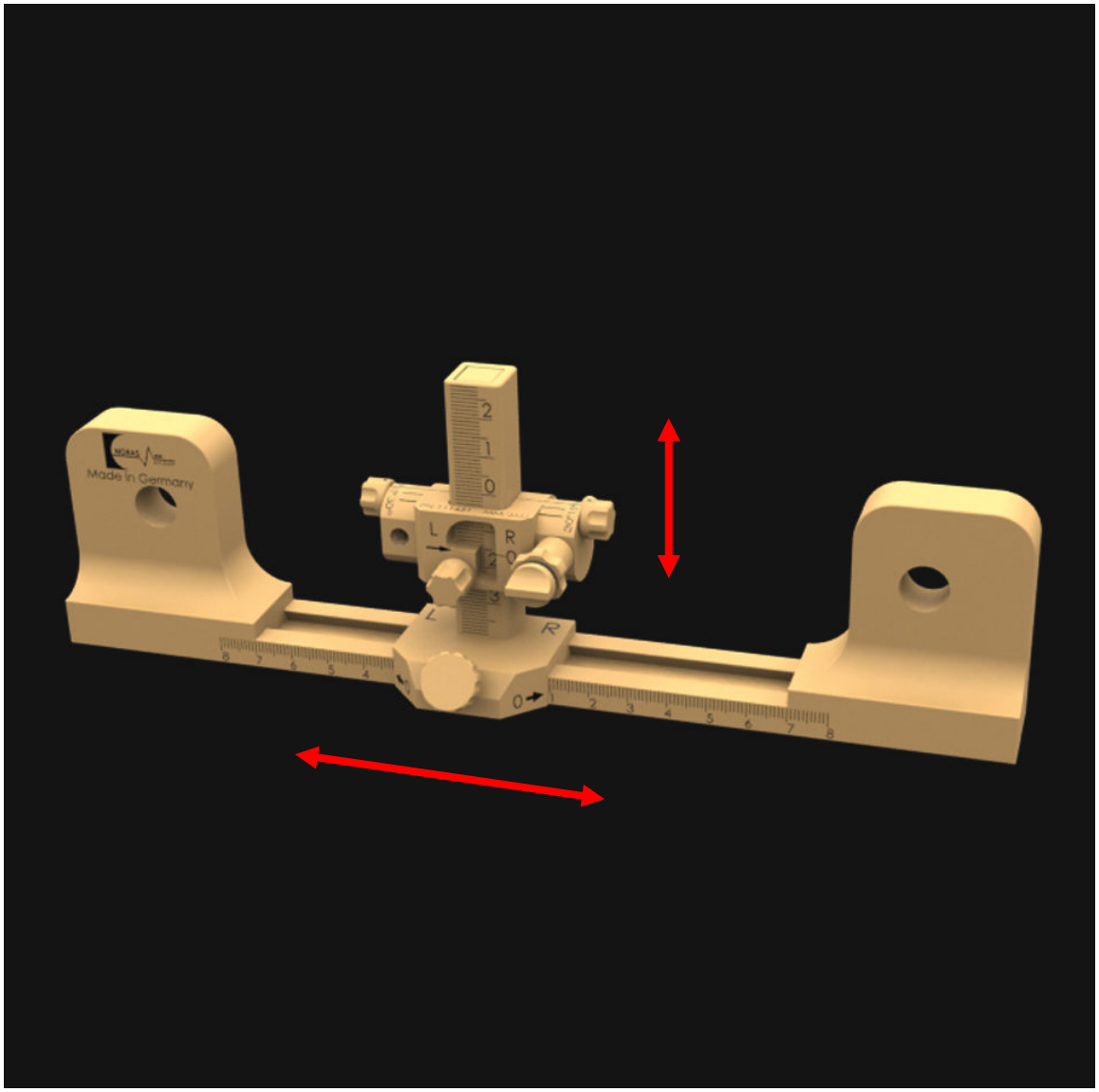
6. Select the “distance” tool again and measure the distance between the lesion and the reference line that you copied in step 5. Please note these measurements on a separate piece of paper.

In this example the Post & Pillar positioning unit has to be moved 6 mm from the marker zero position to posterior (because the patient is lying in the prone position).

7. In order to determine the shift from head to feet (Post & Pillar positioning unit to the left or to the right), view the slice position of the marker and lesion at the transversal slices.

8. The lesion you have chosen in step 5. is located in our example on slice position S27.1 (superior), the marker in slice position I2.9 (inferior). In order to reach the lesion, you have to move the Post & Pillar positioning unit 27.1+2.9mm = 30mm.

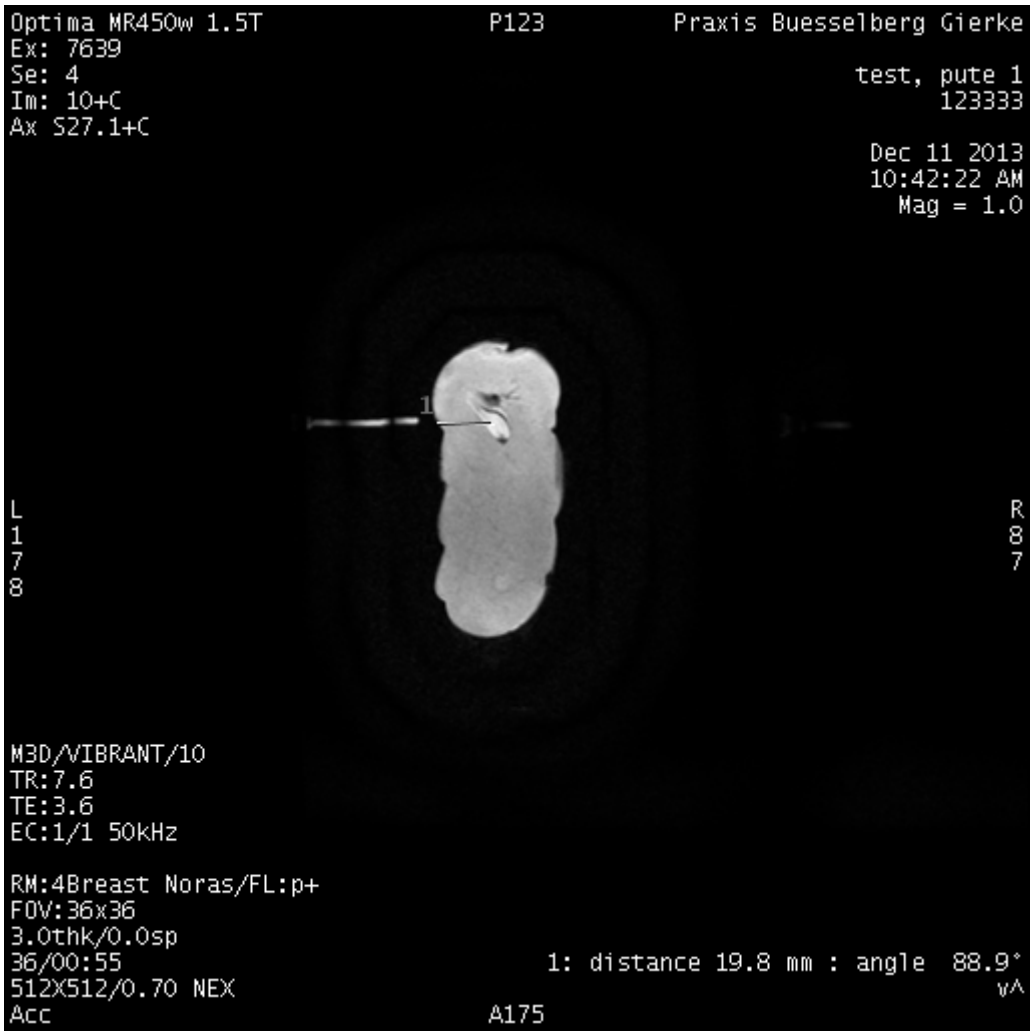
9. Move the Post & Pillar positioning unit with the marker according to the calculated coordinates.



10. Perform a control scan in order to check that the marker is located in front of the lesion.

11. Use the “distance” tool again in order to measure the **puncture depth from the surface of the skin to the middle of the lesion** (in this case 19.8 mm). Subtract an **offset**, depending on the biopsy system (normally about **5-10 mm**), in order to position the cannula lie in front of the lesion.

Now puncture the breast with the trocar using this offset-corrected depth (starting at skin surface). Afterwards pull the needle out of the trocar and insert the plastic-bar into the cannula instead. The plastic-bar causes less artifact than the needle and prevents blood back-flow into the cannula.



12. Perform a control scan in order to check that the end of the needle is positioned in front of the lesion.

The further biopsy may then be carried out by authorized personnel.

	**Control scan shows large or no image distortion**
	Please pay attention to removing the metal trocar when inserting the cannula. When using a plastic cannula the metal trocar has to be replaced by the provided plastic stick.

	**Needle penetration at incorrect location**
	Please take care of using a needle with the appropriate size/gauge as well as the corresponding needle guide sleeve. In case of extreme small needle sizes, the lesion may be missed. In case of extreme large needle sizes, there is a risk of damage to the needle.

 G24	**Insufficient penetration depth**
	Please take care of using a needle with the appropriate length. Using a too short needle, you might not reach the lesion.

Perform the biopsy in accordance with the instructions of your needle and/or vacuum manufacturer.

After completion of the biopsy, clean the device parts as described in chapter 7 “Cleaning, Disinfection and Sterilization”.

 G25	**Danger of penetration through the breast** Should, under exceptional circumstances, the needle be bent while in the breast (e.g. if the needle should strike one of the three horizontal slats after penetrating through the breast), clip off the distally deformed needle end with a suitable, MR-compatible tool and remove the remaining trocar. Retraction of the needle with the bent end section would injure the breast.

	**Danger of bruising** Be absolutely sure to loosen the slat lateral plates before withdrawing the breast. That way, bruises or injuries to the patient can be avoided.

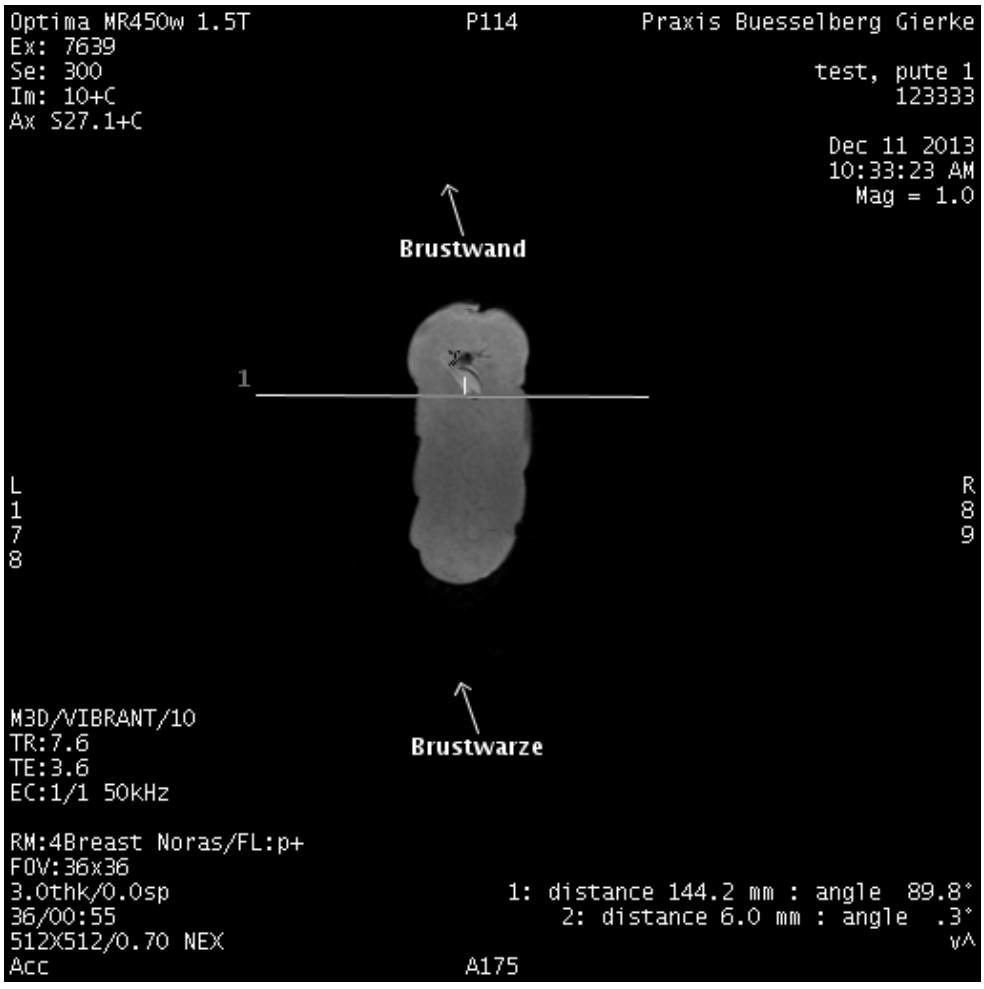
 G26	**Danger of injury** Before loosening and withdrawing the breast, you must remove all instruments. If all instruments are not removed, you may injure the breast of the patient.

b) Angulated, manual calculation of coordinates for the MR-supported breast biopsy with the NORAS Post & Pillar Biopsy Unit on GE MR systems

Perform the steps 1. to 10. from the user manual for the straight, manual calculation of coordinates. If you notice during the straight biopsy that, for example, one of the bars of the grid is in the way of the biopsy, or if you prefer to continue with an angulated biopsy for any other reason, you can also work with an angulation of 15 or 30 degrees toward the top or the bottom.

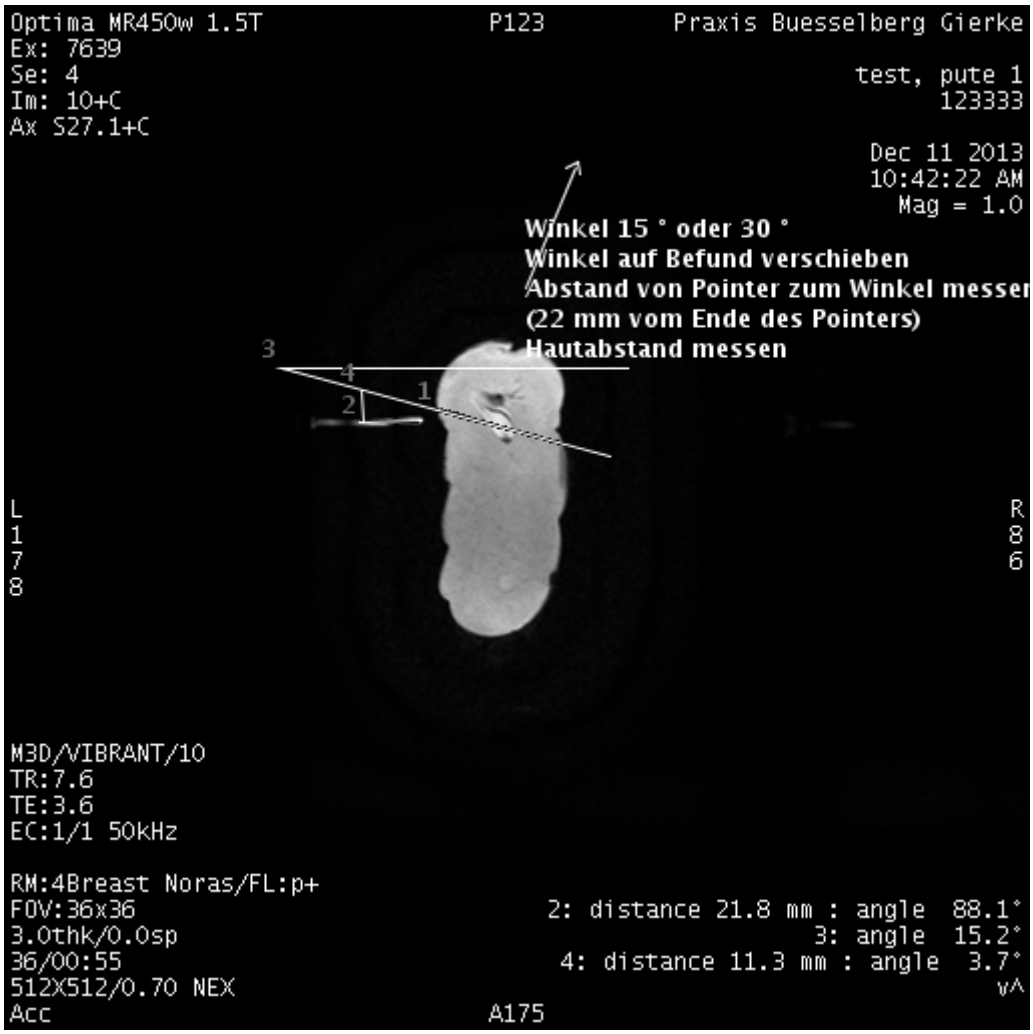
13. Now, an angle of 15 degrees (in this example) has to be drawn to the original marker line. To do so, one needs to use the “angle“ tool.

14. Draw the first line, in this example from right to left, through the marker toward the lesion.



15. Draw the second line with an angle of 15 degrees from left to right. This can also be done slightly underneath the first line.

16. The second line has to have appropriate length toward the right so it lasts at least underneath the pivot point of the Post & Pillar marker. You can also extend that line afterwards by pulling its right endpoint.



17. Now, go ahead and move the second line (which forms an angle of 15 degrees with the first line) so that it has its left endpoint in the center of the lesion. Then, left-click the second line. Finally, hold down the left mouse key and move the line.

18. Choose the “distance” tool und draw the new line with a length of 22 mm from the tip of the marker to the back, where the pivot point of the mechanic is located.

19. With an additional line, measure the distance from the pivot point on the marker (22 mm behind the tip) to the line with 15 degrees angle. This is the amount you need to move the Post & Pillar positioning unit.

20. After movement and angulation of the marker, perform a control scan in order to check that the marker points at the lesion. Now, determine similarly to step 11. the **puncture depth from the skin surface to the center of the lesion**.

21. After the puncture with the trocar, perform another control scan in order to check that the end of the cannula lies right in front of the lesion.

The further biopsy may then be carried out by authorized personnel.

	**Control scan shows large or no image distortion**
	Please pay attention to removing the metal trocar when inserting the cannula. When using a plastic cannula the metal trocar has to be replaced by the provided plastic stick.

	**Needle penetration at incorrect location**
	Please take care of using a needle with the appropriate size/gauge as well as the corresponding needle guide sleeve. In case of extreme small needle sizes, the lesion may be missed. In case of extreme large needle sizes, there is a risk of damage to the needle.

 G24	**Insufficient penetration depth**
	Please take care of using a needle with the appropriate length. Using a too short needle, you might not reach the lesion.

Perform the biopsy in accordance with the instructions of your needle and/or vacuum manufacturer.

After completion of the biopsy, clean the device parts as described in chapter 7 “Cleaning, Disinfection and Sterilization”.

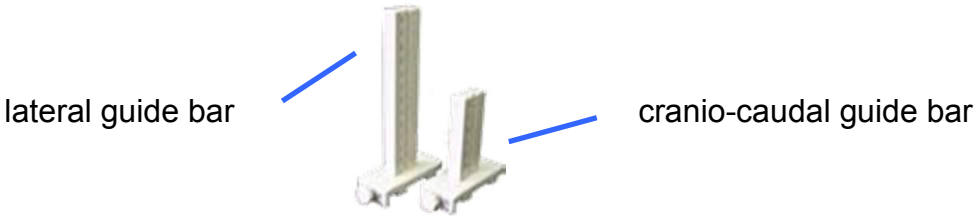
 G25	**Danger of penetration through the breast** Should, under exceptional circumstances, the needle be bent while in the breast (e.g. if the needle should strike one of the three horizontal slats after penetrating through the breast), clip off the distally deformed needle end with a suitable, MR-compatible tool and remove the remaining trocar. Retraction of the needle with the bent end section would injure the breast.

	**Danger of bruising** Be absolutely sure to loosen the slat lateral plates before withdrawing the breast. That way, bruises or injuries to the patient can be avoided.

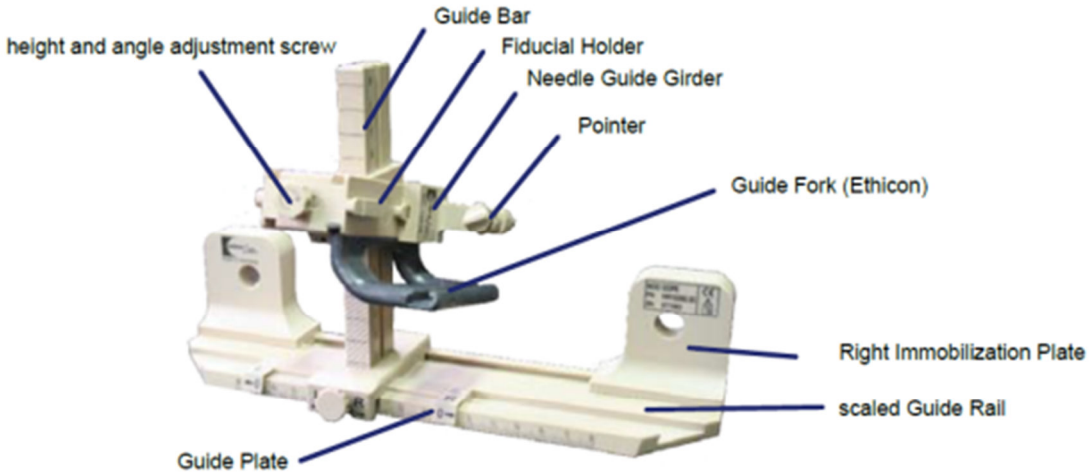
 G26	**Danger of injury** Before loosening and withdrawing the breast, you must remove all instruments. If all instruments are not removed, you may injure the breast of the patient.

6.1.1 Post & Pillar Adapter for Ethicon Mammotome® MR

In application with the Ethicon Mammotome® MR-Vacuum System, we offer a modified positioning device with similar functions as the standard version. In order to support the doctor with the stabilization of the Mammotome holster the modified unit is larger. Two different sized guide bars replace the telescope bar. Please also regard Ethicon directions when using this device!



The needle guide girder with mounted pointer has to be inserted in the right lateral splint of the fiducial holder until it locks in. After that, the fiducial holder can be placed on one of the guide bars (lateral/cranio-caudal).

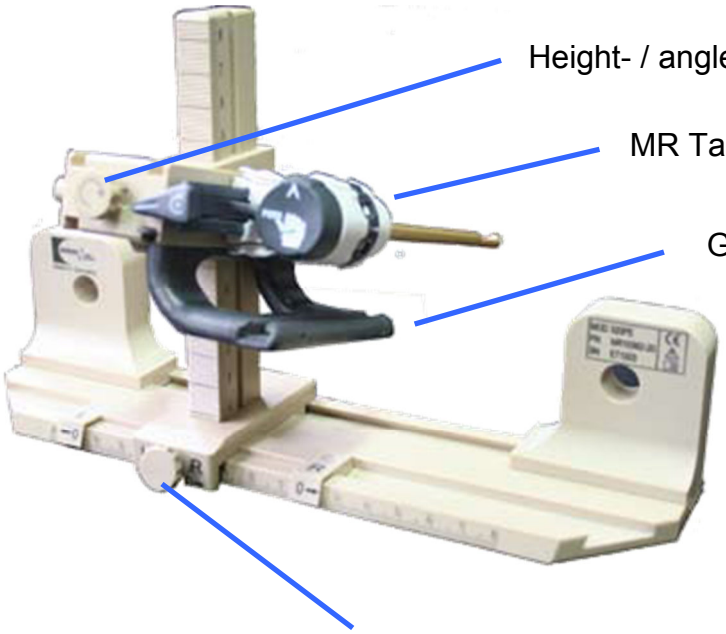


The vertical “0” position is indicated by the upper edge of the fiducial holder and the “0” base at the guide bar. For height adjustment (anterior/posterior) please adjust the fiducial holder at the requested position and close the adjustment screw.

The modified positioning device is now installed and “0” based. In order to extract markers and coordinates please follow chapter instructions.

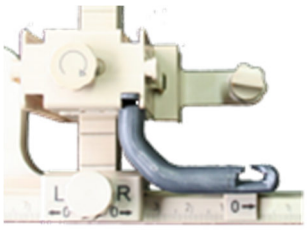
For horizontal biopsies (no angulations, 0°) the handling of the NORAS Mammotome® MR Adapter is equal to the standard NORAS positioning devices. For angulated biopsies please note that the center of rotation varies from the standard NORAS positioning devices. The center is located 68 mm (not the usual 22 mm) behind the head of the pointer, which is visible in the MR image. In order to calculate the coordinates you have to subtract 68 mm from the position of the head of the pointers line.

For angulation use, turn the adjustment screw at the front of the fiducial holder until you are able to change the angle. Anterior as well as posterior angulations are possible for 15° and 30°. After the angulations adjustment close the adjustment screw slowly until the new position of the fiducial holder is fixated.

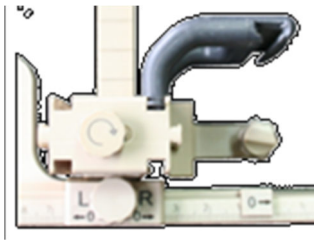


Targeting Set (Ethicon)

In case of a very anterior lesion position the guide fork (Ethicon) can be set on a higher position, which enables another 17 mm anterior access. Please note that in this procedure the holster must be held upside down so that tissue samples will fall downwards.



Vertical and horizontal
„0“ position of the pointer

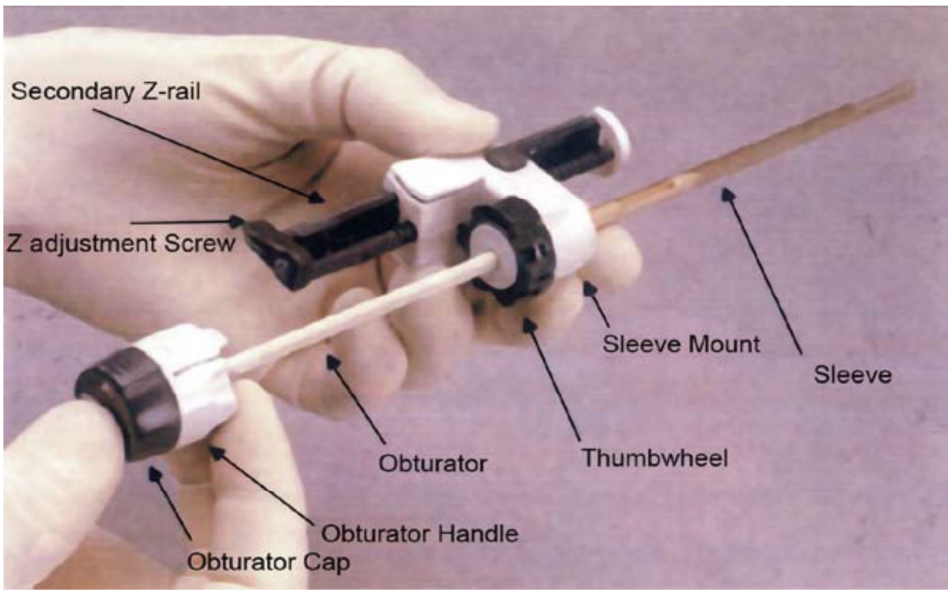


Lowest adjustable
position of the pointer

After adjustment of the calculated coordinates please perform a control scan with installed Ethicon guide fork. The scan shows the pointer as a light line, which points towards the lesion. The distance between skin and lesion along this line indicates the insertion depth of the needle inside the breast.

Following the position and control scans (see chapter 6.1), the needle guide girder with pointer can be replaced from the fiducial holder. Later the Targeting Set will take its place.

For selecting and instruction information about the specific Targeting Set, please look at the manual of your vacuum system manufacturer.



Bodily injuries due to accessories

The NORAS Mammotome® MR Adapter may only be used if the operator´s manual of the vacuum system manufacturer was read and understood.

Note

The NORAS Mammotome® MR Adapter is compatible with the Ethicon Holder for the reception of the Ethicon Mammotome® MR Universal Targeting Sets MRU11S, MRU11X, MRU08S and MRU08X.

Danger of injury and delocalization

The NORAS Mammotome® MR Adapter is the guidance and positioning of the Targeting Set as well as the vacuum system. In addition, it can carry the Targeting Set individually into the control scan. The NORAS Mammotome® MR Adapter is not capable of carrying the weight of the vacuum system individually. During the control scan, the Mammotome Targeting Set must not slip

6.1.2 Post & Pillar Adapter for SenoRx EnCor®

Please follow the instructions of chapter 6.1 „With Post & Pillar Biopsy System“ and the operator´s manual of your vacuum biopsy gun.

6.1.3 Post & Pillar Adapter for Suros ATEC™

Please follow the instructions of chapter 6.1 „With Post & Pillar Biopsy System“ and the operator´s manual of your vacuum biopsy gun.

6.1.4 Post & Pillar Adapter for Bard Vacora®

Please follow the instructions of chapter 6.1 „With Post & Pillar Biopsy System“ and the operator´s manual of your vacuum biopsy gun.

Please note! (regarding from chapter 6.1.2 until 6.1.4)

When using our needle guide sleeves 18-14G or the custom-made 11G needle guide sleeve the Post & Pillar Marker is to be disinfected and does not have to be auto-claved. The needle guide sleeves need to be sterilized (autoclave method or similar). Please see chapter 7 “Cleaning, Disinfection and Sterilization“.

When using a vacuum gun in combination with our Post & Pillar adapters the Post & Pillar marker has to be sterilized according to our sterilization instruction. When using a steam autoclave please follow the Post & Pillar marker instruction for sterile filling. It is recommended to perform the adjustment of the coordinates with both the needle guide (contained in the set) and the inserted Post & Pillar marker.

After setting the height adjustment note the adjusted height. In order to place the cannula for puncturing, exchange the guidance bracket with the inserted Post & Pillar marker against the sterile adapter without Post & Pillar marker.

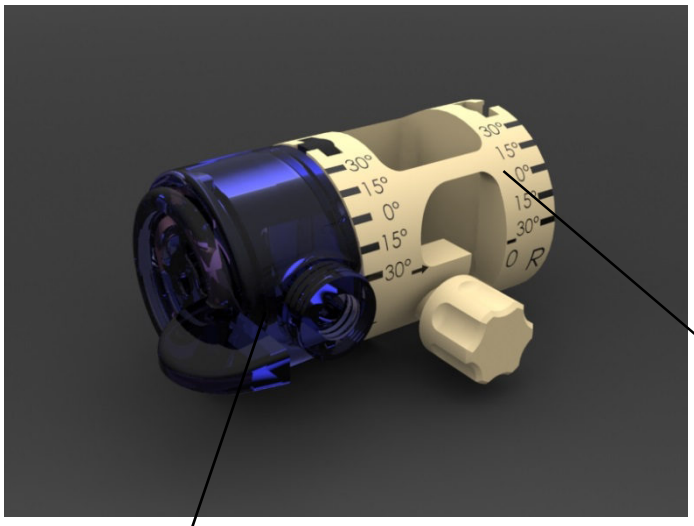
A control scan the tissue sample can now be taken.

Please make sure that when using plastic cannulas that no artifact is noted after removing the trocar. Close the cannula with the provided accessory (plastic stick) after removing the trocar.

The plastic stick is then to be removed and the puncture or wire localization can be performed through the cannula.

6.1.5 Multi-Purpose Needle Hub Assembly

Beside the conventional needle carrier you can also use a sterile, disposable, needle guide Multiple Hub Assembly from Invivo). The Multiple Hub Assembly will be held in the guidance bracket (MR10014-MHA) and will be fixed with twist-on connector. The Multiple Hub Assembly can be used with all biopsy needles distributed by NORAS MRI products GmbH.



6.2 With Grid Biopsy System

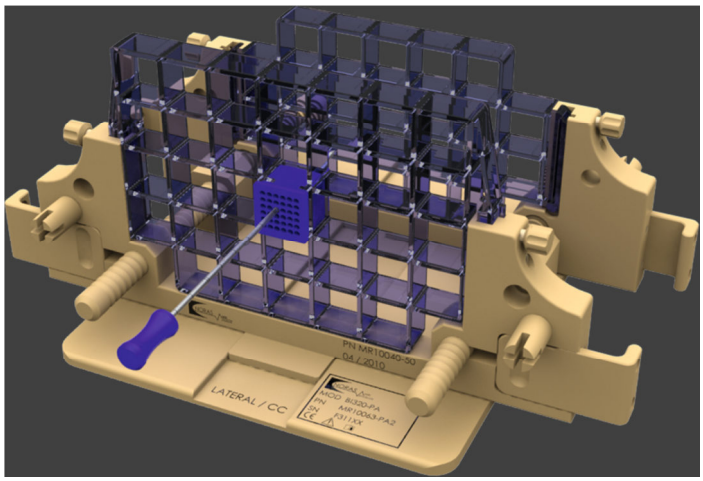
	**Permanent damage to the system**
	The system may only be assembled by trained medical personnel. Incorrect assembly and operator errors made by untrained personnel can permanently damage individual parts of optional components and of the device itself.

 G20/G40	**Training of personnel**
	The users must be trained before using the device (detailed training of the personnel for existing components).

The localization process with medio-lateral alignment of the fixation unit, lateral access and the use of the sagittal slices is next described. This applies for the use of the system with the grid for the examination of a single breast. In the case of the simultaneous biopsy of both breasts (lateral access) use a second fixation unit and a second grid on the other side and proceed in the same way.

Medial and lateral access:

Push the fixation plate with the disposable medial grid plate onto the shorter raster bars of the base plate (Ref. 111292) as far as it goes.



Slide the second fixation plate with the disposable lateral grid onto the longer raster bars of the base plate (marked „Lateral/CC“) up to the stop. Insert the base plate into the round pits of the insertion plate in the patient rest.

After aligning the complete fixation unit in medio-lateral direction, slide the fixation plate until the end of the raster bars. The fixation unit is now open as far as possible.

For medial access, insert the blocking plate into the patient rest of the side of the breast which is not to be biopsied. Now position the patient on the patient rest and immobilize the breast to be biopsied by pressing the fixation plates on the raster bars against the breast.

Be careful to ensure that the patient can lie as comfortable as possible during the entire procedure. You now have medial access below the blocking plate or lateral access from the outside.

Cranial/caudal access:

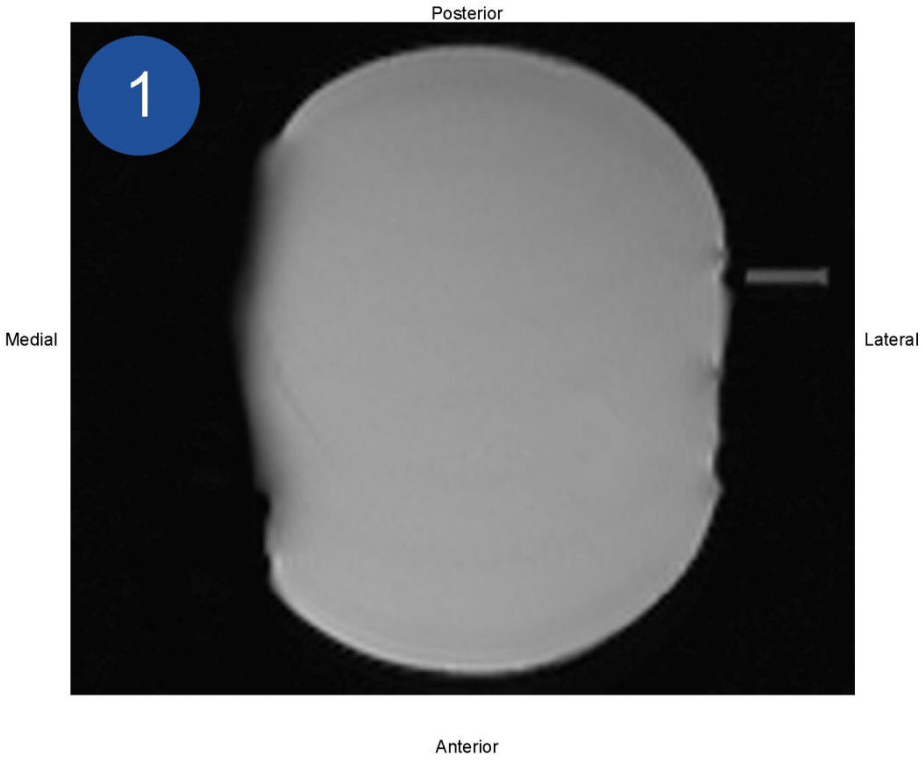
Slide the fixation plate with the medial slat plate (re-usable) or with a second disposable medial grid onto the shorter raster bars of the base plate (Ref. 111292) as far as it goes. Slide the second fixation plate with a disposable medial grid onto the longer raster bars of the base plate (marked “Lateral/CC”) up to the stop. Proceed as described above (access medial and lateral).

Please note that when the biopsy device is turned into the cranio-caudal direction, the MRI images must be made in the axial or transversal direction to correspond with the following description.

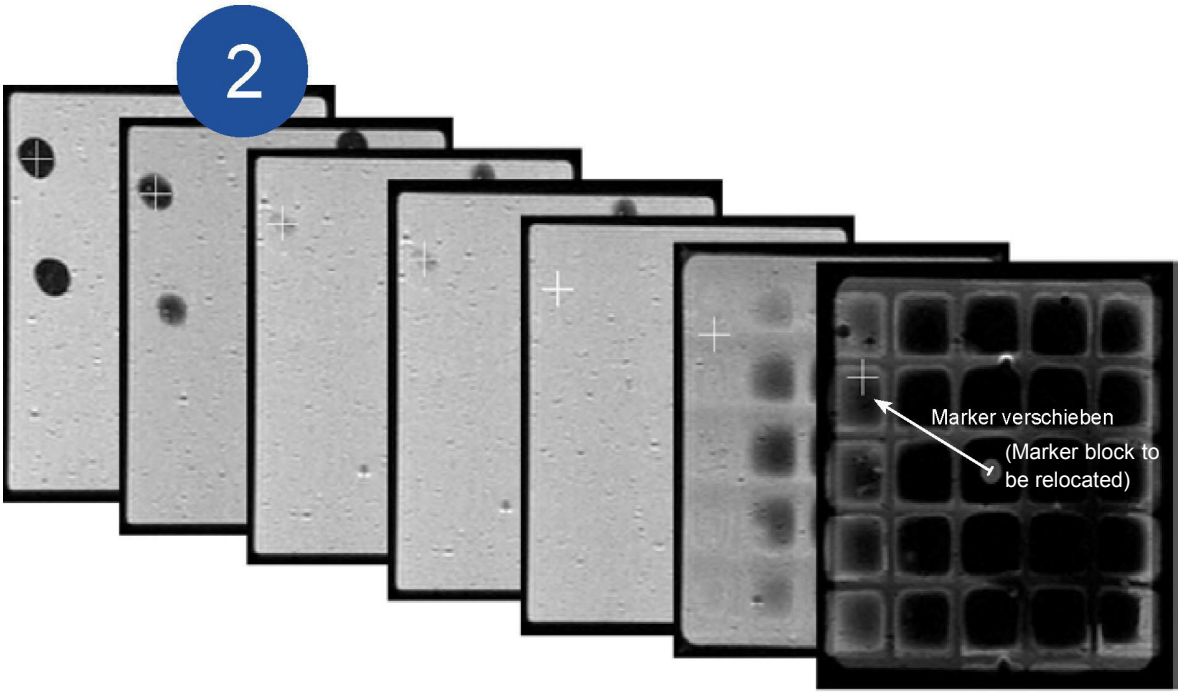
	**Skin contact**
	During the examination some parts of the breast may come into contact with the surface of the base plate with the low probability. Before each examination of the patients, the base plate must be covered with a clinical cloth.

 G23	**Needle penetration at incorrect location**
	The breast must be correctly immobilized. If the breast is not immobilized properly, it might slip and the data delivered by the MRI might be inaccurate.

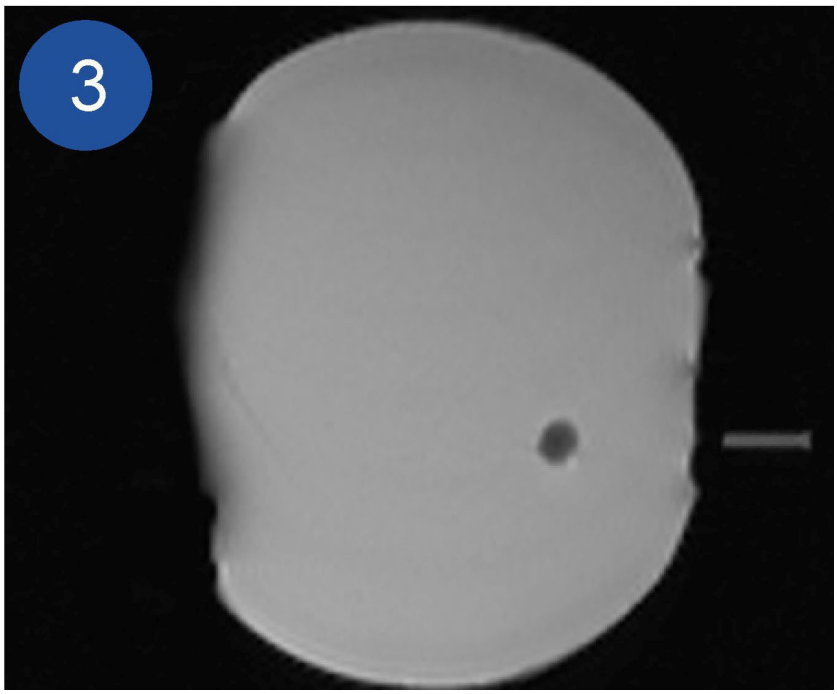
- Ensure that as much breast tissue as possible is held between the medial slat plate and the lateral grid.
- Insert the marker block supplied into the grid fixation plate.



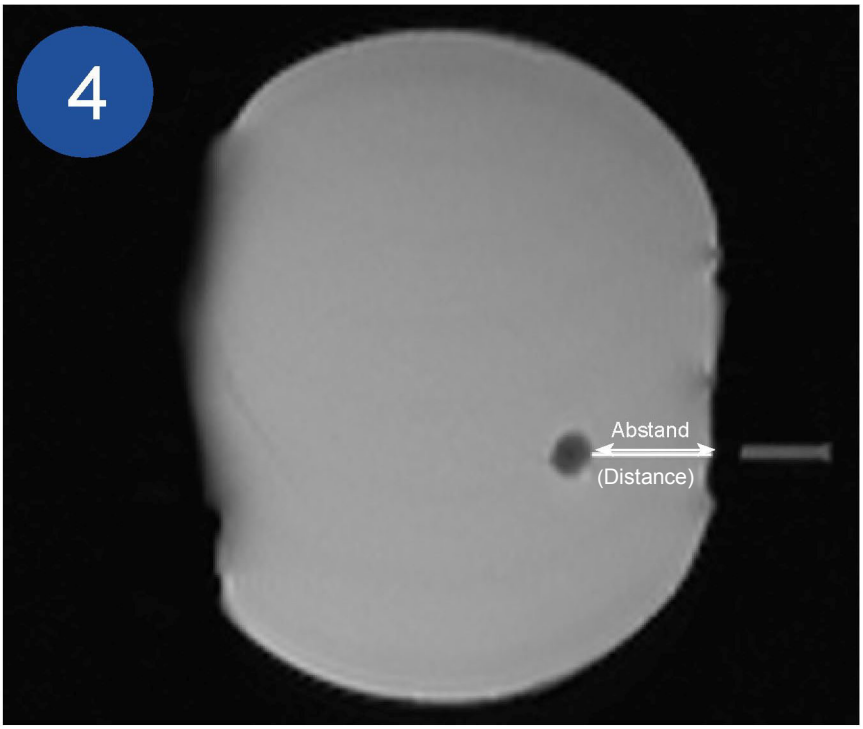
- Detect the marker block and the lesion in the MRI using sagittal slices.
- Mark the lesion with a permanent auxiliary point from the software toolbox of your MRI system.
- Copy/paste the point into all slices.
- Go to the outer lateral or medial slice and look for the grid indentation (the indentation is best viewable when sufficient tissue is placed into the square grid holes).
- Search for the copied point and the marker block pointer.
- Replace the marker block into the grid hole where the marked point is viewable.

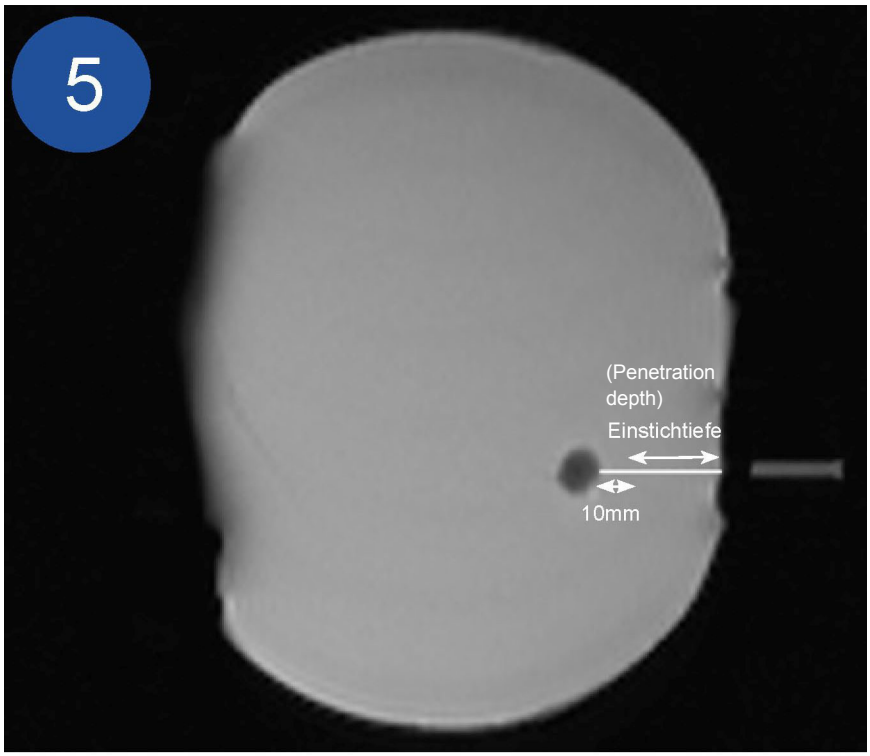


- After the axial or coronal scan the layer of the lesion and marker block can be verified in order to determine the exact puncture hole.
- In general, it is sufficient to be close to the lesion when inserting a localization wire.



- When the marker block and the lesion are in the same plane determine the **distance between the skin and the lesion** using your toolbox.





- Push the needle block with the desired diameter (12G, 14G or 18G) into the corresponding opening in the compression plate and, using the toolbox, determine the desired penetration point on the needle block.
- Select the needle block with the proper size needle and mount these in the calculated position. Select a needle with an appropriate length to reach the lesion. Consider to add the offset an approximately 25 mm to the distance skin lesion. Insert the needle to a position approx. 10 mm in front of the lesion.
- If possible (needle diameter to be considered) set a local anesthesia using the block slot that has been determined. Remove the needle block and apply an additional anesthesia, if necessary. This may be done using a bigger needle by slightly cutting the tissue with a sterile scalpel. Especially with lesions close to the surface this might be very important to avoid a delocalization.

- When replacing the needle block place the cannula and remove the trocar. After the control scan the wiring or removing of tissue may be performed. Please make sure no artifact is notable when using plastic cannulas and removing the trocar. Having removed the trocar close the cannula using the provided equipment (sterile plastic stick). This prevents blood from entering the cannula.
- Perform a control scan with the inserted needle. Set the distance shown in the toolbox between the needle point and the lesion on your needle scale and penetrate with the needle to the lesion.

Perform the biopsy in accordance with the instructions of your needle and/or vacuum manufacturer.

	**Control scan shows large or no image distortion**
	Please pay attention to removing the metal trocar when inserting the cannula. When using a plastic cannula the metal trocar has to be replaced by the provided plastic stick.

	**Needle penetration at incorrect location**
	Please take care of using a needle with the appropriate size/gauge as well as the corresponding needle guide sleeve. In case of extreme small needle sizes, the lesion may be missed. In case of extreme large needle sizes, there is a risk of damage to the needle.

 G24	**Insufficient penetration depth**
	Please take care of using a needle with the appropriate length. Using a too short needle, you might not reach the lesion.

After completion of the biopsy, clean the device parts as described in chapter 7 “Cleaning, Disinfection and Sterilization”.

 G25	**Danger of penetration through the breast** Should, under exceptional circumstances, the needle be bent while in the breast (e.g. if the needle should strike one of the three horizontal slats after penetrating through the breast), clip off the distally deformed needle end with a suitable, MR-compatible tool and remove the remaining trocar. Retraction of the needle with the bent end section would injure the breast.

	**Danger of bruising** Be absolutely sure to loosen the slat lateral plates before withdrawing the breast. That way, bruises or injuries to the patient can be avoided.

 G26	**Danger of injury** Before loosening and withdrawing the breast, you must remove all instruments. If all instruments are not removed, you may injure the breast of the patient.

6.2.1 Grid Needle Block Adapter for Ethicon Mammotome® MR

For use with the Ethicon Mammotome® MR the NORAS company offers reusable needle block adapters made of PEEK. These ensure the compatibility of the Mammotome® MR Universal Targeting Sets MRU11S, MRU11X, MRU08S and MRU08X with the NORAS grids. The positioning process is described in chapter 6.2. After the successful positioning process of the needle block adapter and the control scan, please follow the Mammotome® MR manual from Ethicon in order to accomplish the biopsy procedure.

6.2.2 Grid Needle Block Adapter for SenoRx EnCor®

For use with the SenoRx EnCor® Mammo Biopsy System the NORAS company offers reusable needle block adapters made of PEEK. These ensure the compatibility of the SenoRx EnCor® Biopsy System (EnCor cannulas and probes with 7G, 10G and 12G) with the NORAS grids. The positioning process is described in chapter 6.2 After the successful positioning process of the needle block adapter and the control scan, please follow the SenoRx EnCor® Biopsy System manual in order to accomplish the biopsy procedure.

6.2.3 Grid Needle Block Adapter for Suros ATEC™

For use with the Suros ATEC™ Biopsy System the NORAS company offers reusable needle block adapters made of PEEK. These ensure the compatibility of the Suros ATEC™ Biopsy System (cannulas and probes with 9G) with the NORAS grids. The positioning process is described in chapter 6.2 After the successful positioning process of the needle block adapter and the control scan, please follow the Suros ATEC™ Biopsy Systems manual in order to accomplish the biopsy procedure.

6.2.4 Grid Needle Block Adapter for Bard Vacora®

For use with the Bard Vacora® Vacuum Biopsy System the NORAS company offers reusable needle block adapters made of PEEK. These ensure the compatibility of the Bard Vacora® Vacuum Biopsy System (cannulas and probes with 10G) with the NORAS grids. The positioning process is described in chapter 6.2 After the successful positioning process of the needle block adapter and the control scan, please follow the Bard Vacora® Vacuum Biopsy System manual in order to accomplish the biopsy procedure.

6.3 MR-Mammography

	**Permanent damage to the system**
	The system may only be assembled by trained medical personnel. Incorrect assembly and operator errors made by untrained personnel can permanently damage individual parts of optional components and of the device itself.

In the following, the mammographic imaging process with the medio-lateral alignment of two fixation and immobilization devices for the simultaneous diagnosis of the left and right breast is described.

- Insert base plates into the insertion plate coil on the right and left sides in such a way that two immobilization plates with one slat lateral plate each can be used medio-laterally on both sides (laterally with the curved slat lateral plate supplied, also horizontally for possible improved patient comfort).

	**Skin contact**
	During the examination some parts of the breast may come into contact with the surface of the base plate with the low probability. Before each examination of the patients, the base plate must be covered with a clinical cloth.

- Position the patient on the patient rest and immobilize the breast to be examined by pressing the slat lateral plates on the variable position bars in such a way that the patient can lie as comfortable as possible during the entire examination.
- Ensure that as much breast tissue as possible is held between the slat lateral plates.
- Use the toolbox of your MRI system to determine ROI, FOV and type of sequence.
- Perform the MR-mammographic procedure.

	**Danger of bruising**
	Be absolutely sure to loosen the slat lateral plates before withdrawing the breast. To do so, simultaneously push the left and right slides and pull the lateral slat plate outwards. That way, bruises or injuries to the patient can be avoided.

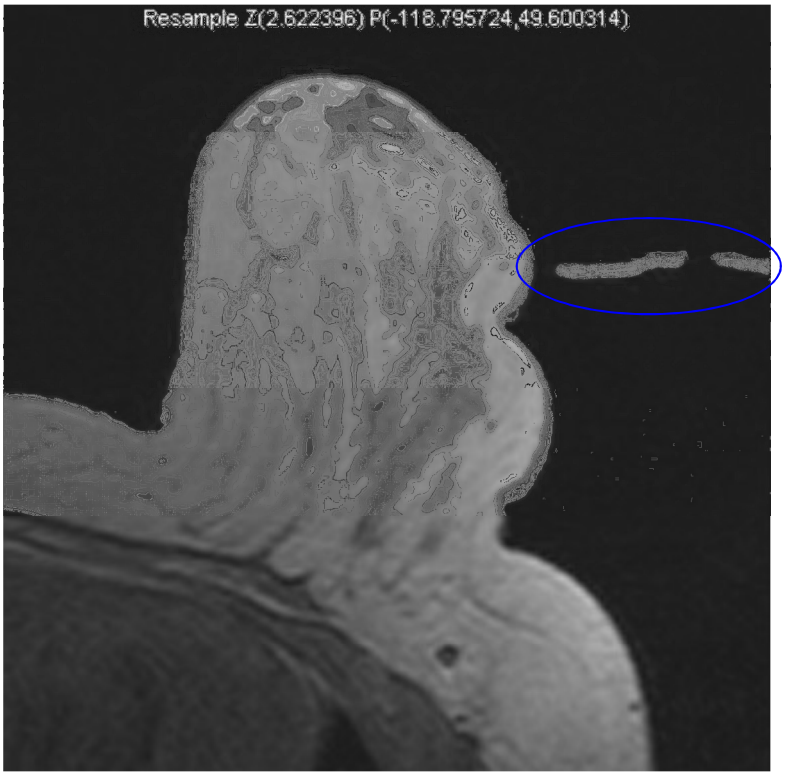
6.4 Safety Information

Please consider the following when using the **Breast Biopsy 4-Channel Coil BI 320-PA-GE 1.5T**:

 G30	**Damage to the coils** When transporting the insertion plate coil, carry it only by its housing, not by its cables. Never carry the patient pad coil by its loops and do not bend it. Connection cables must not be bent or knotted. Defective coils (including their cables, shield traps and plugs) must not be used.

	**Permanent damage to the system** The system may only be assembled by trained medical personnel. Incorrect assembly and operator errors made by untrained personnel can permanently damage individual parts of optional components and of the device itself.

In order to enable reliable navigation, the marker must be displayed in the MRI image as a straight line. If the marker is imaged with a kink or offset, similar to that, shown in the adjoining illustration, repeat the image with a reversed phase code direction.



7 Cleaning, Disinfection and Sterilization

WARNING:	The procedure must be followed as described. In case of inadequate cleaning, disinfection or sterilization, you carry the risk of infection. Non-compliance with the cleaning instructions may destroy the system. No warranty service will be provided for damages due to improper disinfecting. Please always wear protective gloves and carefully comply with the application times for Hepatitis B and HI viruses (See the instructions for use of the respective disinfectant solution).
Limitations on re-processing:	Frequent processing can have an impact on these products (color changes), but do not affect the function of the product.

Note

Frequent processing can have an impact on these products (color changes), but do not affect the function of the product.

Note

Please always wear protective gloves and comply with the application times for Hepatitis B and HI viruses (See the instructions for use of the respective disinfectant solution).

INSTRUCTIONS	
Point of Use:	Remove excess soil with disposable cloth/paper wipe.
Storage and Transport:	No particular requirements. It is recommended to perform the processing of the product as soon as possible after its use. The products must be transported in a closed container.
Preparation for Cleaning:	No particular requirements. If necessary, the assembly must be disassembled into its individual components. Needle blocks and needle guide sleeves could possibly be pre-cleaned by syringe or water nozzle. Cannulas and holes must be connected in accordance to rinse body. Pay attention to correct flow. Preparation with H_2O_2 or enzymatic cleaner could be done.

Cleaning (automated): All parts can be cleaned by machine, the **exception** cases are: - coil cables and plugs - patient rests - patient pad coils (PPC) - bottom array coil (FBC) - breast cushion - head rest - vacuum mattresses	**Equipment:** Washer/disinfector **Detergent:** Example **alkaline detergent such as Neodisher® MediClean forte 0,2-1,0 vol. % (2-10 ml/l) (Dr. Weigert) at 50°C.** For this purpose, all agents, which have been approved and released by the Robert Koch Institute (RKI) can be used in accordance with the instructions on their labels. **Procedure:** 1. Load components such that hinges are open and cannulations and holes can drain. For needle blocks and needle guides a pre-cleaning by means of syringe or water jet may be necessary. 2. Run cycle, minimum **5 minutes** clean and **5 minutes** rinse. 3. When unloading, check cannulations, holes etc. for complete removal of visible soil. If necessary, repeat cycle or use manual cleaning.	**Applicable only for:** Biopsy Set consists of: Base Plate, Fixation Plate (lateral/medial), Slate Plate (vertical & horizontal), Curved Slate Plate (vertical & horizontal), Post & Pillar Positioning Unit, Post & Pillar Marker, Needle Guide Sleeve Set, Grid Localization, Needle Block Set, Grid Markerblock, Blocking Plate, Autoclave Box, Needle Guide, Post und Pillar Adapter for Ethicon®, SenoRx®, ATEC™, Vacora®, Grid Needle Block Adapter for Ethicon®, SenoRx®, ATEC™, Vacora®

Disinfection (automated): All parts can be disinfected by machine, the **exception** cases are: - coil cables and plugs - patient rests - patient pad coils (PPC) - bottom array coil (FBC) - breast cushion - head rest - vacuum mattresses	**Disinfectant: Depending on RDG and Vario-TD-program you can select on disinfectant which has been approved and released for automated disinfection.** **Procedure:** If automated disinfection is employed, a final rinse at **90°C** for **5 minutes** may be used to effect thermal disinfection. The parts such as needle guides and needle blocks can be disinfected in accordance with the same procedure in an ultrasonic bath. The assembly must be disassembled into its individual components, so that an optimal disinfection is guaranteed.	**Applicable only for:** Biopsy Set consists of: Base Plate, Fixation Plate (lateral/medial), Slate Plate (vertical & horizontal), Curved Slate Plate (vertical & horizontal), Post & Pillar Positioning Unit, Post & Pillar Marker, Needle Guide Sleeve Set, Grid Localization, Needle Block Set, Grid Markerblock, Blocking Plate, Autoclave Box, Needle Guide, Post und Pillar Adapter for Ethicon®, SenoRx®, ATEC™, Vacora®, Grid Needle Block Adapter for Ethicon®, SenoRx®, ATEC™, Vacora®

Cleaning and Disinfection (manual): The following parts **may not** be inserted in immersion baths and be held under running water: - **all coil types** - all coil cables and plugs - bottom array coils (FBC) - patient pad coils (PPC) The above mentioned products can be wiped cleaned with a fluff-free moistened cloth. Due to possible material incompatibility, abrasive cleaners or other organic solvents and solvent-based cleaning agent (e.g. benzene, alcohol, stain removers) may not be used.	**Detergent:** Example **Sekusept® PLUS (Ecolab) 4.0 vol. %, Korsolex® Plus 3.0 vol. % with exposure time of 15 minutes**. For this purpose, all **aldehyde-free** surface disinfectants which have been approved and released by the RKI and the VAH can be used in accordance with the instructions on the label. The cleaning of the parts could be done manually in immersion or ultrasonic bath for **10-30 minutes**, preferable at temperatures of up to **50°C**. **Procedure:** 1. Rinse excess soil from components. 2. Using soft brush, apply detergent solution to all surfaces ensuring that hinged components are cleaned in both open and closed positions. 3. The part is held under running water for **5 minutes**. In this case, the running water must flow through the cannulas. The blind holes must be repeatedly filled and emptied. 4. The parts must be cleaned as long as no visible blood or tissue residues more on the products to be seen. For manual disinfection, it is advisable to insert the parts (for expected parts see left column) in the solution immediately after use. Ensure that the parts are completely submerged in the solution. Take the parts from the solution after the described time	**Applicable only for:** Biopsy Set consists of: Base Plate, Fixation Plate (lateral/medial), Slate Plate (vertical & horizontal), Curved Slate Plate (vertical & horizontal), Post & Pillar Positioning Unit, Post & Pillar Marker, Needle Guide Sleeve Set, Grid Localization, Needle Block Set, Grid Markerblock, Blocking Plate, Autoclave Box, Needle Guide, Post und Pillar Adapter for Ethicon®, SenoRx®, ATEC™, Vacora®, Grid Needle Block Adapter for Ethicon®, SenoRx®, ATEC™, Vacora®

	15 minutes and rinse by water (the quality of water must be at least equal to drinking water, better would be using aqua. Demineralized water). Changing in color due to continuous disinfection cannot be excluded, but can be largely prevented by sufficient rinsing after each use. The solution is distributed on the surfaces by a fluff-free cloth. The disinfectant permeates the dirt particles and because of mechanical forces (pressure, abrasion), this ensures effective cleaning. Additionally, the wiping motion ensures that spores, which are resistant to the disinfectant, will be removed. The cloth must be replaced after the disinfection in order to prevent the spreading of the spores on other areas. Moreover, it is essential that the wiping solution is renewed regularly (daily).	

	**Danger of destruction**
	The coils must not be cleaned in immersion baths or held under running water. Non-respect of the cleaning instructions may cause the destruction of the coils!

	**Danger of destruction** The coils must not be disinfected in immersion baths or held under running water. Non-respect of the disinfection instructions may cause the destruction of the coils!

Drying:	When drying is achieved as part of washer/disinfector cycle, do not exceed **50°C**.
Maintenance, Inspection and Function Testing:	Blunt or damaged parts should be discarded. Hinged parts: Check for smooth movement of hinge without excessive “play“. Locking (ratchet) mechanism should be checked for action. All parts: Visually inspect for damage and wear. Cutting edges should be free of nicks and present a continuous edge. Check components with long slender features (particularly rotating components) for distortion. Where components form part of a larger assembly, check assembly with associated components.
Packaging:	**Singly:** A standard packaging material may be used. Ensure that the pack is large enough to contain the instrument without stressing the seals. **In sets:** The parts may be loaded into dedicated instrument trays or general-purpose sterilization trays. Ensure that cutting edges are protected and do not exceed the maximum loading per tray. Wrap the trays using appropriate method. See also guidance of DGSV, RKI and DIN EN ISO 11607-1.

Sterilization:	**Steam sterilization:**
The following parts may be sterilized **neither** on basis of **STERRAD® not** steam sterilization: - coil cables and plugs - patient rests - patient pad coils (PPC) - bottom array coil (FBC) - breast cushion - head rest	**Only** the **following items** may be subjected to **steam sterilization**: Biopsy Set consists of: Base Plate, Fixation Plate (lateral/medial), Slate Plate (vertical & horizontal), Curved Slate Plate (vertical & horizontal), Post & Pillar Positioning Unit, Post & Pillar Marker, Needle Guide Sleeve Set, Grid Localization, Needle Block Set, Grid Marker-block, Blocking Plate, Autoclave Box, Needle Guide, Post und Pillar Adapter for Ethicon®, SenoRx®, ATEC™, Vacora®, Grid Needle Block Adapter for Ethicon®, SenoRx®, ATEC™, Vacora® **Procedure:** 134°C; 3.04 bar; 5 min The effectiveness of steam sterilization according to the procedure mentioned above has been validated by Dr. Schwarzkopf.

Warning

Markers must be emptied prior to sterilization!

Storage:	Safe, dry, dust-free and protected from light Constant temperature (23°C +/- 2°C) Constant humidity (below 60% rel. humidity)
Additional Information:	When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.
Manufacturer Contact:	See chapter 10

 G28	**Danger of destruction** Improper disinfection may result in malfunction of the device. Non-respect of the disinfection instructions may cause the destruction of the device! No warranty service will be provided for damages due to improper disinfection.

 G10/G34	**Danger of infection** The disinfection instructions must be followed. In case of inadequate disinfection the risks of infection arise to user and / or end user.

 G29	**Danger of destruction** Improper sterilization may result in malfunction of the device. Non-respect of the sterilization instructions may cause the destruction of the device! No warranty service will be provided for damages due to improper sterilization.

 G11/G35	**Danger of infection** The sterilization instructions must be followed. In case of inadequate sterilization the risks of infection arise to user and / or end user.

8 Maintenance, Storage and Waste Disposal

8.1 Maintenance

Prior to each use, all components of the **Breast Biopsy 4-Channel Coil BI 320-PA-GE 1.5T** must be visually inspected and controlled for breakage, cracks and wear off.

Patient Rest	Check for breaks or cracks
Patient Pad Coil / cable and plug	
Frame Breast Coil / cable and plug	
Immobilization and Fixation Unit	

Defective products must not be used. In such a case, please contact NORAS MRI products GmbH.

Comply with the cleaning, disinfection and sterilization instructions.

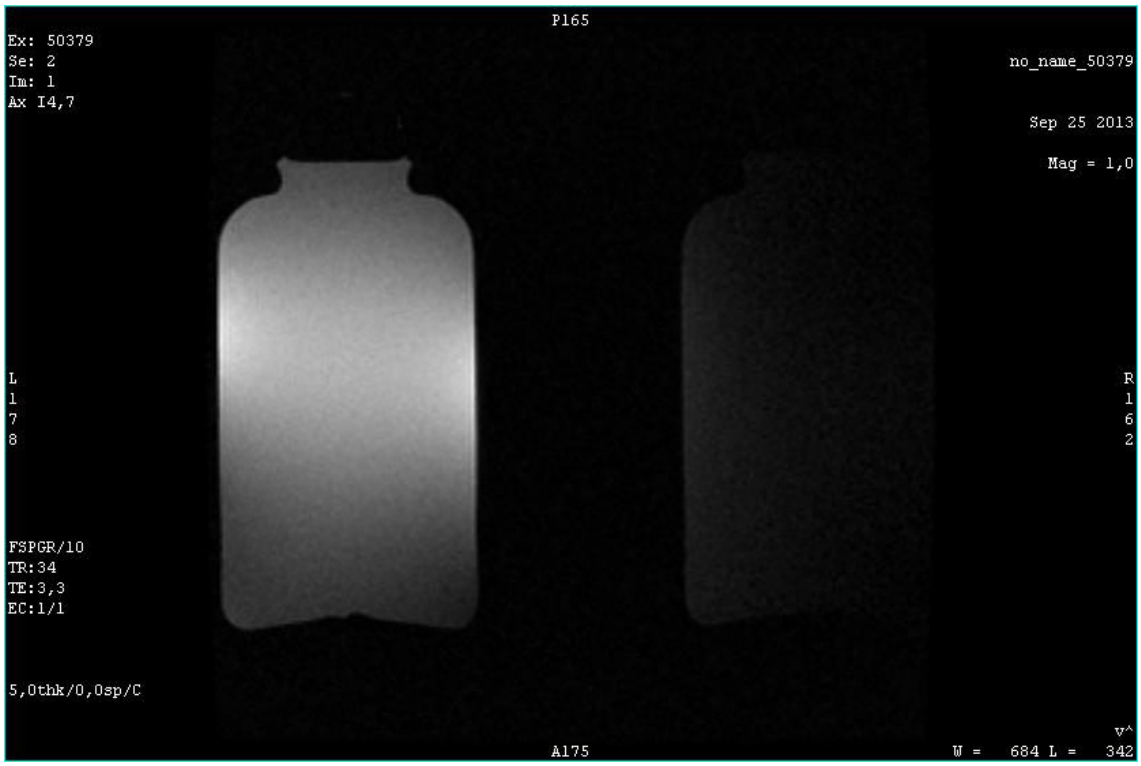
We recommended that you have a single channel test of the coils performed on a monthly basis using the specified test program of the MRI system.

Functional tests

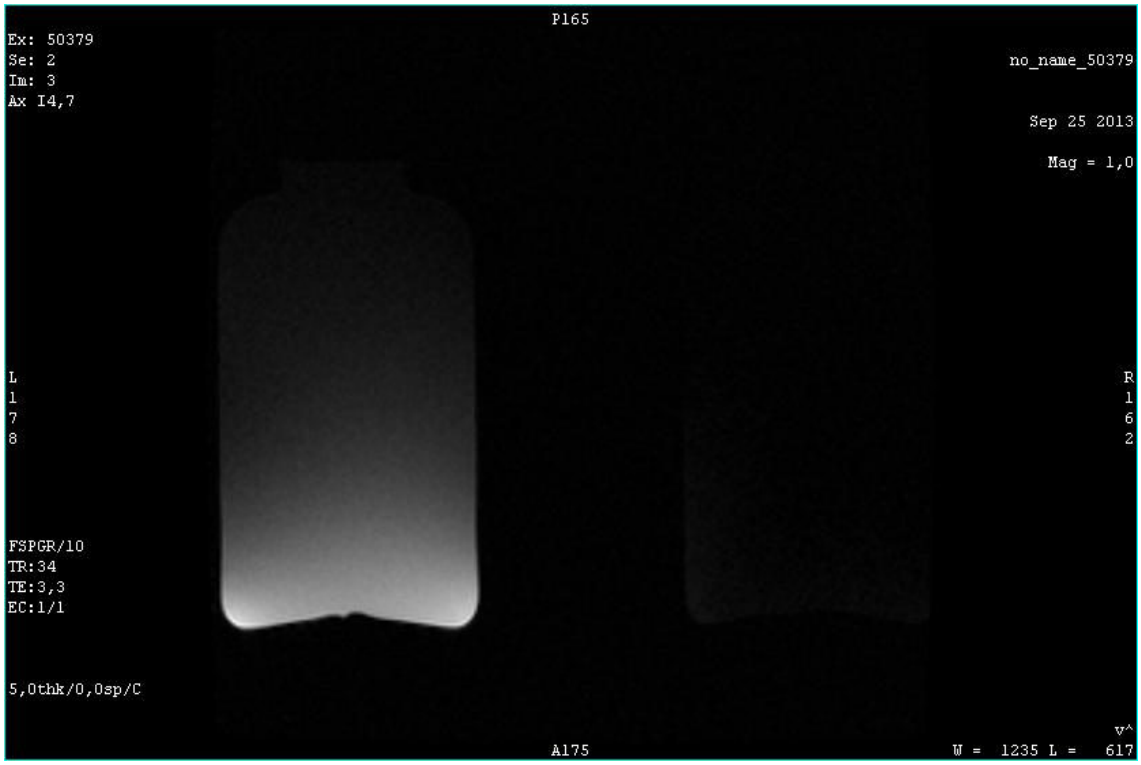
In case coil malfunctions are suspected, the operator may perform the functional test described below.

After positioning an axial slice through two phantom bottles, the four channels of the coil should be shown similar to the following illustrations.

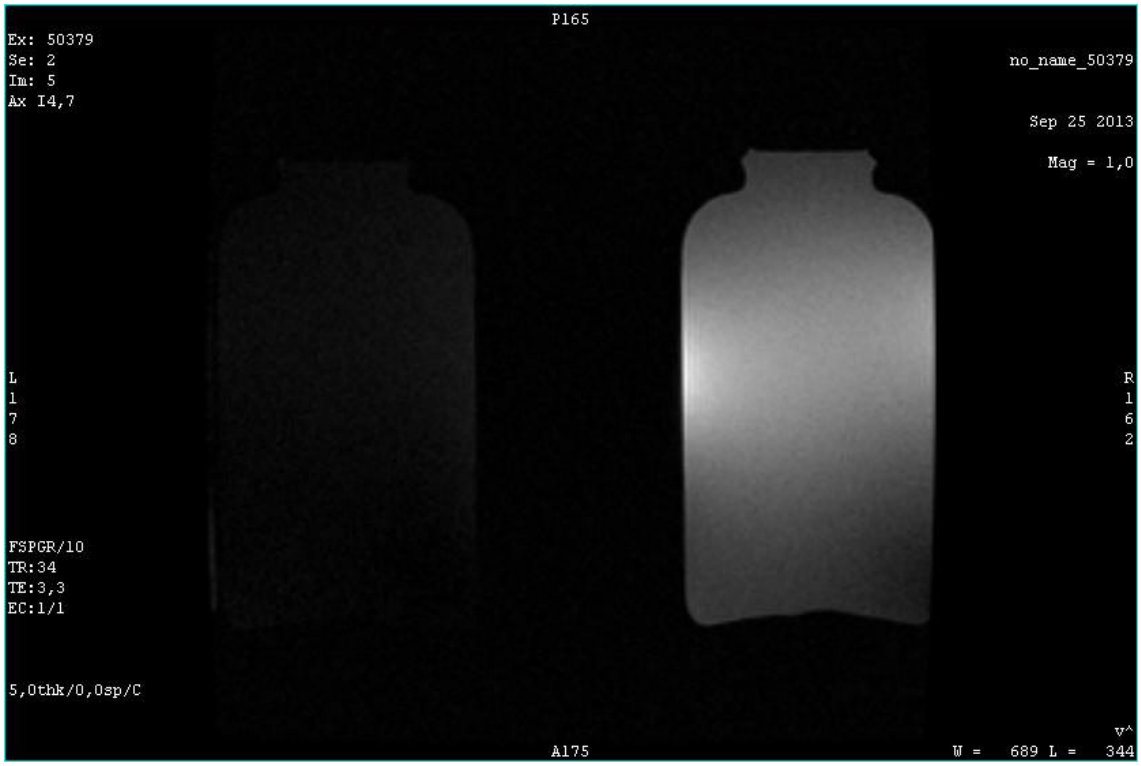
Display of channel 1:



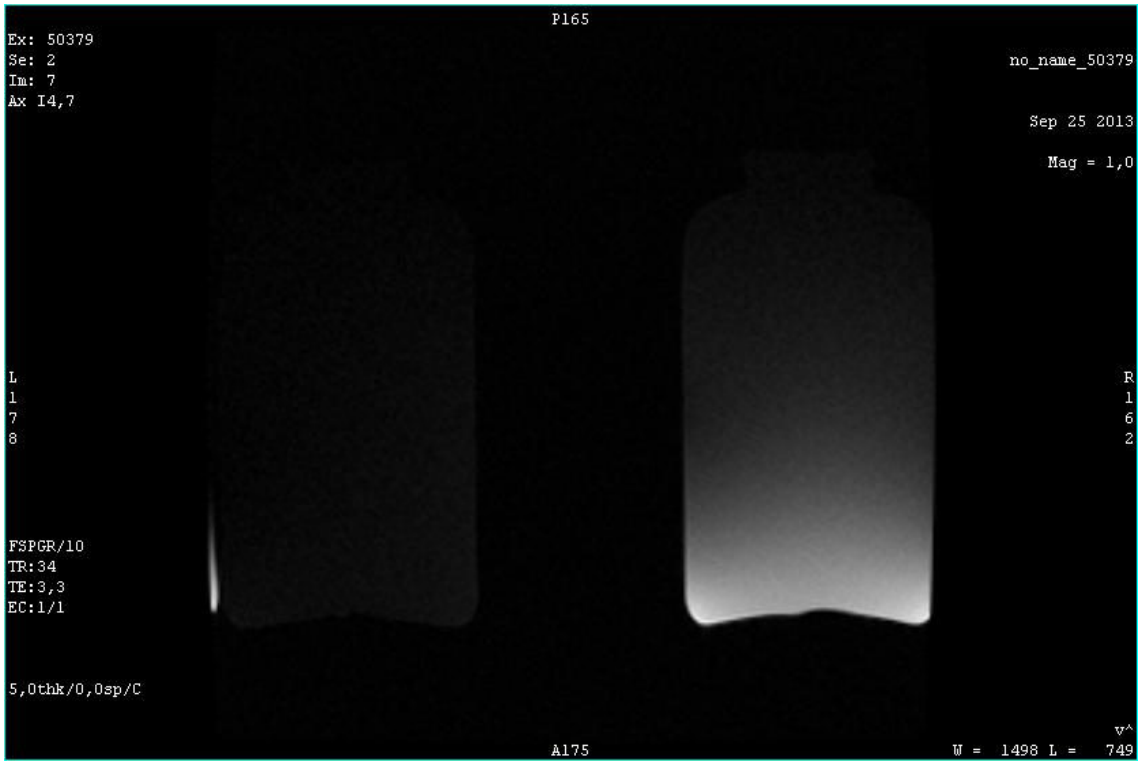
Display of channel 2:



Display of channel 3:

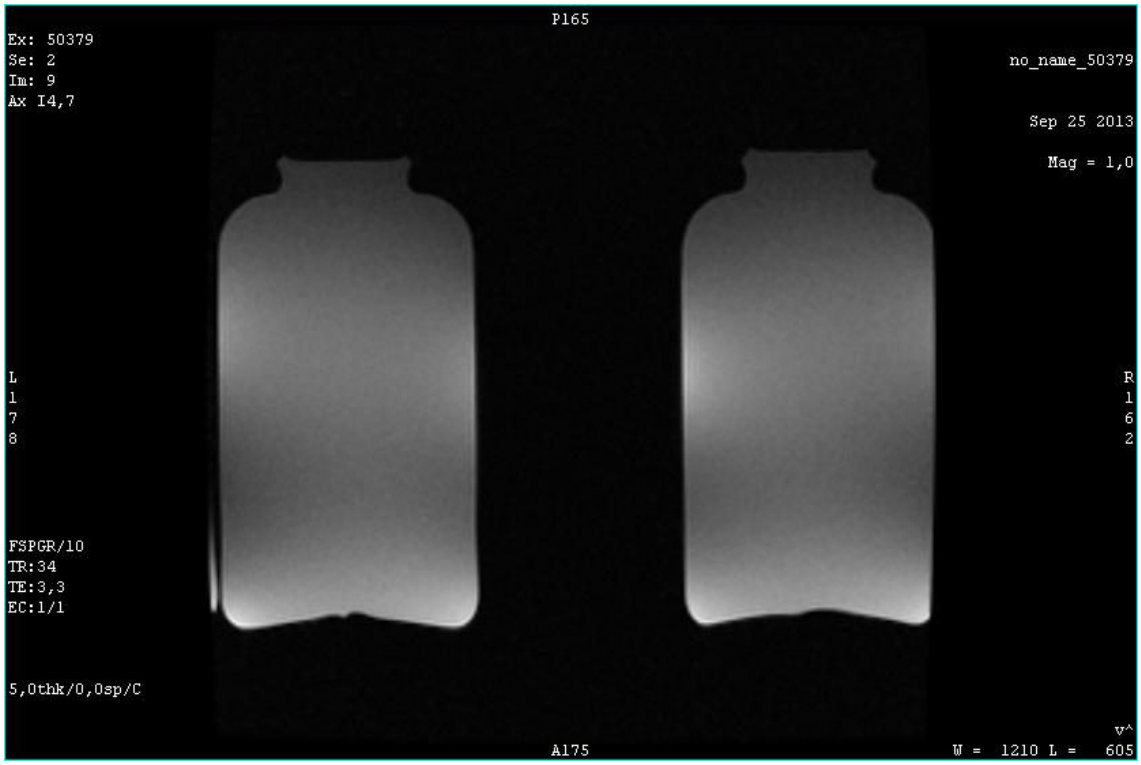


Display of channel 4:



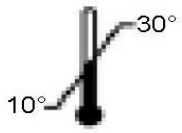
The illustration shows that the four coils channels are producing a good quality, artifact-free signal.

Display of four channels:



If the images produced during your measurement appear significantly different from the above (e.g. the image contains bands or one channel with a clearly weaker signal, then a coil may be defective. In this case, please contact the NORAS MRI products GmbH.

8.2 Storage

	Following its use and the required cleaning, disinfection and sterilization, the device should be stored at room temperature in a dust-free, UV radiation-protected location (min. 10°C, max. 30°C). In the case of re-sterilized needle guide sleeves, you must not exceed the maximum storage period (currently 6 months if stored in single or double packaging in protected storage in dust-tight containers, cabinets, drawers or similar places).

- Relative Humidity: Min.10%, Max. 95%
- Air Pressure: Min. 500 hPa, Max.1060 hPa

8.3 Waste Disposal

All of the materials used in the manufacture of the system components can be conveniently recycled and therefore do not present any particular or unusual hazards during their disposal.

Prior to disposal, the system must be disinfected as described above to eliminate any risk of infection.

Following their final use, the patient pad coil and the frame breast coil should be returned to the manufacturer for disposal.

We would be happy to provide you with additional information about disposal upon request.

9 Technical Specification

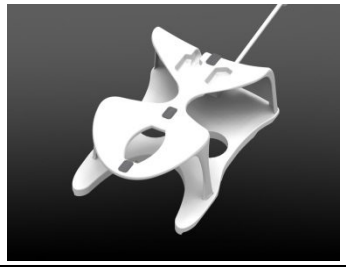
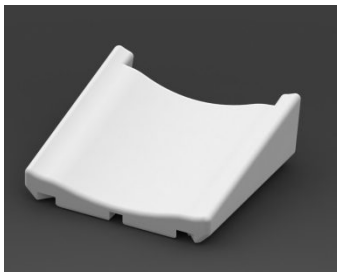
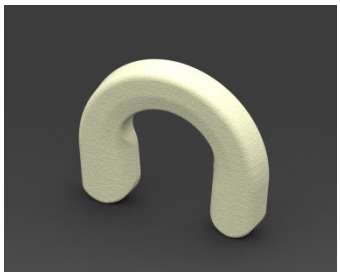
9.1 Historical Device Data

Designation (model/type) Breast Biopsy 4-Channel Coil BI 320-PA-GE 1.5T 117693	**Product type / Device type (according to UMDNS / DIMDI)** Surface coil MR (17-542)
Manufacturer: NORAS MRI products GmbH Leibnizstrasse 4 97204 Hoechberg Germany	**Supplier:** NORAS MRI products GmbH Leibnizstrasse 4 97204 Hoechberg Germany
Operation type ☒ active ☐ non active	**Test / Control (time limits / type)** ---
Product class / Device class IIa (per MDD annex IX, chapter III, clause 3, paragraph 3.2, rule 10)	**Intended purpose according to information provided by the manufacturer:** The device is intended for use during the MRI examination of the female breast. Biopsies can also be made with the system.
Identification number of notified body (CE -marking): 0123	**Serial numer**

9.2 Performance Data

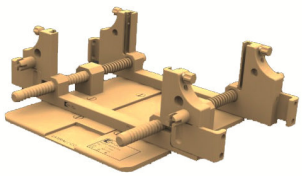
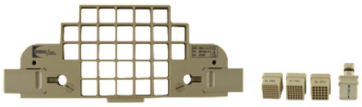
Operating temperature:	Corresponding with the air-conditioned room temperature of the MRI room
Storage temperature:	Room temperature
Protection class:	II
Weight:	Approx. 10 kg (according to accessories)
Dimensions:	774 x 470 x 196 mm
Interfaces:	Electrical: GE MRT Mechanical: MRT Patient Rest
Maximum operating time of coils:	Continuous operation
Field of view (maximum):	160 mm x 320 mm x 160 mm

9.3 Parts List

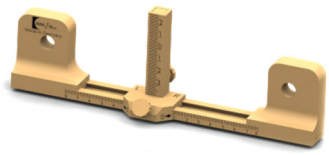
Breast Biopsy 4-Channel Coil BI 320-PA-GE 1.5T		**117693**
Patient Rest		117720
Breast Cushion		114971
Head Rest		117758
Patient Pad Coil for GE 1.5T		117721

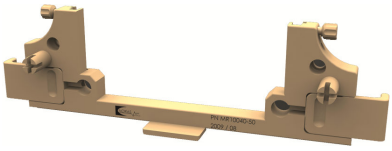
9.4 Options and Accessories

9.4.1 Compilation of the Biopsy System

Description	Illustration	Ref.
Base Unit for all NORAS BI320 Biopsy Systems		112663
Post & Pillar Biopsy System: lateral, medial, cranio-caudal		111449
Grid Biopsy System: lateral, medial, cranio-caudal		111456
Grid Biopsy System Height Adjustable: lateral		112658

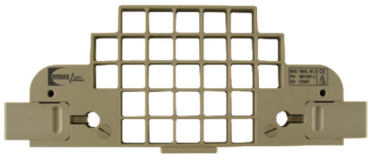
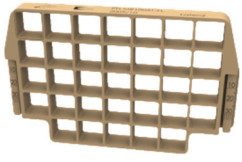
9.4.2 Accessories for Post & Pillar Biopsy System

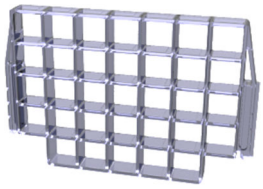
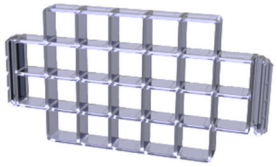
Description	Illustration	Ref.
Post & Pillar Positioning Unit with Telescope Bar: autoclavable and reusable; Material: PEEK		111259
Post & Pillar Needle Guide: autoclavable and reusable; Material: PEEK; able to be angulated by 15° and 30°		111451
Post & Pillar Marker: autoclavable and reusable; Material: PEEK; (remove marker liquid before autoclaving and refill afterwards)		111300

Description	Illustration	Ref.
Post & Pillar Needle Guide Sleeve Set for 18G, 16G and 13G: autoclavable and reusable; Material: PEEK; (also individually acquirable)		111298
Post & Pillar Needle Guide Sleeves for 18G, 16G, 14G and 12G: disposable in sterile packaging (packaging consists of 5 pieces)		18G 112654 16G 112597 14G 112655 12G 112653
Base Unit Fixation Plate: can be used laterally, medially and cranio-caudally and is used as adapter for the slat plates of the grid (reusable, disposable and for attaching the positioning system)		111242
Slat Plate Vertical: medial, cranio-caudal		117145
Slat Plate Vertical: lateral (only for NORAS BI320)		117139
Slat Plate Horizontal: medial, cranio-caudal		111212

Description	Illustration	Ref.
Slat Plate Horizontal, High: medial, cranio-caudal; for thorax proximity interventions		118144
Slat Plate Horizontal: lateral (only for NORAS BI320)		111301

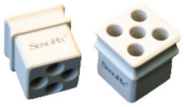
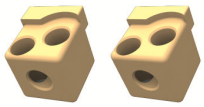
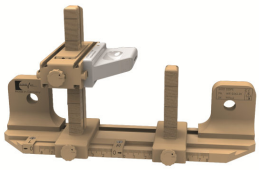
9.4.3 Accessories for Grid Biopsy System

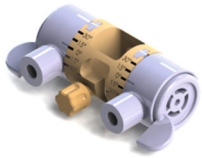
Description	Illustration	Ref.
Grid Markerblock: autoclavable and reusable; material: PEEK; (remove marker liquid before autoclaving and refill afterwards)		111251
Grid Needle Block Set for 18G, 14G and 12G: used for biopsies and wire markers; autoclavable and reusable; material: PEEK		111299
Grid Biopsy Unit: lateral, medial, CC; autoclavable and reusable; material: PEEK		111252
Grid Biopsy Unit Height Adjustable: lateral; autoclavable and reusable; material: PEEK		117143

Description	Illustration	Ref.
Grid Biopsy Unit Height Adjustable: lateral; disposable in sterile packaging (packaging consists of 5 grids)		112235
Grid Biopsy Unit Height Adjustable: medial, CC; disposable in sterile packaging (packaging consists of 5 grids)		112238
Grid Needle Blocks for 18G, 16G, 14G and 12G: disposable in sterile packaging (packaging consists of 5 pieces)		18G 112660 16G 112143 14G 112659 12G 112731

9.4.4 NORAS Adapter for Vacuum Guns

For our biopsy units we offer a large amount of adapters for the traditional vacuum guns. Upon request, we can also manufacture suitable adapters for your system.

Your Vacuum System	Adapter for Grid System	Adapter for Post & Pillar System
 **C.R. Bard Vacora®**	 MR10061-VAC	 MR10062-VAC
 **Suros Surgical ATEC™**	 MR10061-AT	 MR10062-AT
 **SenoRx EnCor®**	 10G: MR10061-SE 7G: on request	 10G: MR10062-SE 7G: 113315
 **Ethicon Mammotome®**	 MR10061-ET	 MR10062-ET2

	Suitable for all NORAS Post & Pillar Biopsy Units: **Guidance Bracket (PEEK) for Invivo Disposable Needle Guidance** **Disposable Needle Guidance (Multi Hub Assembly); not for 7G**	**MR10062-MHA** **113692**

9.4.5 General

Description	Illustration	Ref.
Blocking Plate A blocking plate to raise the alternate breast is required for medial biopsies.		111319
Operator´s Manual BI 320-PA-GE	n/a	118309

	**Bodily injuries due to accessories**
	When using accessories please always observe the manufacturer´s instructions.

10 Important Addresses

Manufacturer (product development and production)

	NORAS MRI products GmbH Leibnizstrasse 4 97204 Hoechberg Germany Telephone: +49 931/2 99 27-0 Telefax: +49 931/2 99 27-20 E-Mail: mri@noras.de Internet: www.noras.de

11 Operator Training Outline

I have reviewed the **Breast Biopsy 4-Channel Coil BI 320-PA-GE 1.5T** Training Outline and understand the topics discussed, and verify that the training outlined is complete.

The training delivered was reflective of the details in the **Breast Biopsy 4-Channel Coil BI 320-PA-GE 1.5T** user manual. I will read (or have read) this appropriate manual, including the Cleaning and Disinfecting section of the manual.

I understand…

the indications for use and the functionality of the **Breast Biopsy 4-Channel Coil BI 320-PA-GE 1.5T**	☐
and am aware of the components of the **Breast Biopsy 4-Channel Coil BI 320-PA-GE 1.5T**	☐
the installation of the **Breast Biopsy 4-Channel Coil BI 320-PA-GE 1.5T**	☐
the complete setup of the **Breast Biopsy 4-Channel Coil BI 320-PA-GE 1.5T**	☐
the connection to the MRI	
the application on patients	☐
the localization and biopsy process	☐
the MR-Mammography	
the cleaning instructions	☐
the disinfection instructions	☐
the sterilization instructions	☐
that it is NOT NORAS' responsibility for timely replacement of worn out parts	☐

Title	Name	Department
Date & Signature:		
☐**Contac Person**	**E-Mail Address:** **Phone No.:**	
Customer:		
Trained by:	**NORAS Application Trainer**	
Date & Signature:		

Your Notes

Your Notes